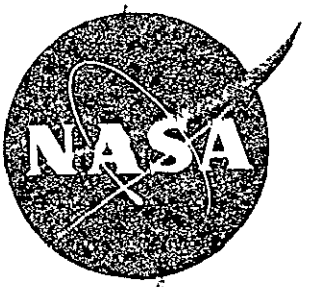
1291

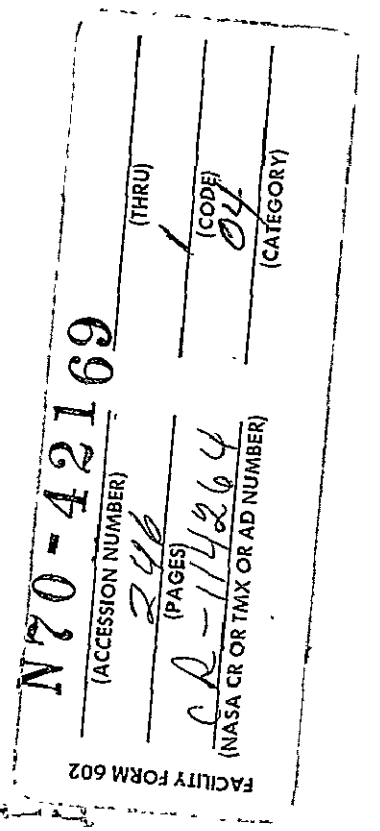
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

GEORGE C. MARSHALL SPACE FLIGHT CENTER
HUNTSVILLE, ALABAMA

30 DECEMBER 1968



QUALITY ASSURANCE REQUIREMENTS MANUAL FOR PLANETARY SPACECRAFT TO BE STERILIZED BY HEATING



GENERAL ELECTRIC
MISSILE AND SPACE DIVISION
Valley Forge Space Technology Center
P. O. Box 8555 • Philadelphia, Penna. 19101

PREFACE

The purpose of this manual is to provide, in a single volume, a source of information and guidelines dealing with quality assurance requirements necessary for the production, assembly, and checkout of a spacecraft to be sterilized by heating in accordance with current NASA sterilization requirements. The manual is based on work performed by General Electric under the present and previous contracts as well as on the NASA MSFC publication SR-QUAL-64-13, but extensive use has also been made of many other available sources. In such cases, a careful attempt has been made to give appropriate credit and to identify the references. No claim for completeness is made. As a matter of fact, the editors are acutely aware of numerous gaps and deficiencies caused by the limitations of their contract and by the state of flux which currently exists in the planetary exploration program and its sterilization requirement implementation and definition.

This manual is not intended for use by itself, but rather as a supplement to a quality assurance manual for the class of spacecraft under consideration. SR-QUAL-64-13 is an example of such a manual. This manual extends the usefulness of general quality assurance manuals to planetary and other spacecraft which must be rendered sterile or require other biological burden control. Thus, it should enable experienced quality assurance personnel to participate in a planetary program by providing a convenient reference volume.

In keeping with the above philosophy, quality provisions and guidelines which are considered common spacecraft practice will not be included, but may be excerpted or referenced where desirable for more complete understanding.

An attempt has been made to include a certain amount of background data on planetary quarantine requirements and microbiology to give quality assurance oriented personnel an appreciation of the problems encountered by personnel outside their area of specialization. Such information is provided in Section 1. This section also covers training programs.

mathematical models, and data bank requirements. Section 2 covers the major elements of a Quality Assurance plan required for a sterilized spacecraft program. Receiving Inspection is discussed in Section 3. Fabrication, subsystem and final assembly are covered in Section 4. The above represent functions which are part of any nonsterilizable spacecraft quality program. In this manual, however, emphasis is placed on the special quality assurance aspects which are required for sterilization, biological monitoring, and related planetary quarantine items. For this reason, conventional quality assurance guidelines are touched upon only briefly because they are available from sources such as SR-QUAL-64-13 and other related documents. Section 5 covers an area which is unique for spacecraft to be sterilized. It covers decontamination and terminal sterilization requirements. Microbiological procedures are discussed in detail in Section 6 and include special facilities requirements. Applicable NASA specifications are either referenced or excerpted for greater convenience throughout this manual.

The rapid pace of progress in the field of bioclean manufacture, assembly and checkout for spacecraft, results in the necessity to include material in this Manual which may be of temporary nature only. This has not ruled out the inclusion of such material because a volume of guidelines must strive to cover all aspects of a problem, even though some approaches and guidelines are temporary. For this reason, users are encouraged to send comments for updating, corrections, and other suggestions concerning this Manual to:

Mr. M. F. Pickard Code R-QUAL-AA
George C. Marshall Space Flight Center
National Aeronautics and Space Administration
Huntsville, Alabama 35812

This Manual was prepared by the Space Systems Organization of the General Electric Company for the George C. Marshall Space Flight Center of the National Aeronautics and Space Administration in partial fulfillment of Contract NAS 8-21139. The Contracting Officer's Representative was Mr. M. F. Pickard.

A manual, such as this, is based on the contribution of many sources and individuals. The major contributors who aided in the preparation of this volume were N. W. Behringer, M. Hammer, M. G. Koesterer, R. J. Kepple, R. Pellicotti, M. R. Stahler and J. St. Leger. The undersigned acted as principal contributors and editors, ably assisted by R. G. Waddell.

E. Fried
J. R. Gillis

King of Prussia, Pa.
December 1968

TABLE OF CONTENTS

TABLE OF CONTENTS (Cont'd)

TABLE OF CONTENTS (Cont'd)

TABLE OF CONTENTS (Cont'd)

LIST OF ILLUSTRATIONS

LIST OF TABLES

SECTION 1
INTRODUCTION

SECTION 1
INTRODUCTION

1.1 SUMMARY

The purpose of this manual is to provide a convenient reference handbook for quality assurance personnel who are engaged in a program requiring planetary quarantine or other biological burden control. This manual is not intended to be used by itself, but in conjunction with the "Biological Handbook for Engineers" (Ref. 1-1) and the appropriate quality assurance guidelines for the class of spacecraft under consideration. The significant new requirements are those introduced by microbiological considerations. Reference 1-1 provides a convenient source for information and reference on microbiological and related background data intended for engineers. The intent here is not to replace training courses for engineering and quality assurance personnel preparatory to their engaging in planetary quarantine related work, but rather to provide a source book.

Training courses are necessary for all personnel required to work on a planetary quarantine subjected spacecraft program. Such courses may range from a brief indoctrination lecture for peripheral personnel to a week-long course for cognizant senior personnel. These are covered and discussed in other parts of this section.

The current emphasis on economic solution of sterilization related activity places the quality assurance engineer in a unique position with respect to achieving such solution on a biologically acceptable spacecraft. Because most of the additional manpower requirements are due to microbiological as well as particulate contamination control, assay and surveillance constraints, this represents an area of potential economic optimization. The quality assurance team in conjunction with the microbiologists and the sterility control group can perform a real service by recommending elimination of unnecessary or ineffectual practices, procedures and facilities. In this context, the work of the microbiology team can be considered a quality assurance and monitoring function performed by specially

trained and specially certified personnel. In fact, microbiology laboratories and personnel must be certified according to NASA Standards. Requirements for such microbiology activities and laboratories are discussed in Section 6.

In order to utilize effectively a body of data based on microbiological assays, in-process inspection, facility certification, personnel qualification, nonconformance reports, etc., an "instant recall" system is necessary. Such a system, within the constraints of planetary quarantine requirements, consists of a data bank and an associated microbiological contamination prediction model. Such a system provides not only traceability for sources of problems, but also provides a reservoir of data for microbial load prediction. Because this requirement is unique for spacecraft systems requiring sterilization, it is covered in some detail in this section.

Other sections deal with "General Background" information, "Planetary Quarantine" and related material.

Paraphrasing some of the Voyager Project definitions of Quality Assurance functions in a planetary program this excerpt summarizes these functions.

> Monitoring and control procedures will be established in the sterilization plans so as to ensure that all event compromising the quarantine constraints will be identified, documented and corrected insofar as is feasible.
>
> Quality Assurance organizations, in cooperation with the cognizant Project System, and cognizant NASA representatives will assure that effective control is exercised by the Capsule Contractors in complying with the quarantine constraints. It is the responsibility of Quality Assurance as a member of this team to interface directly with and monitor the Contractor's Quality Assurance effort so as to assure that all activities are proceeding properly and in accordance with approved specifications, procedures, and plans.

Quality Assurance, as defined above, will act in cooperation with the cognizant NASA representatives in monitoring the following activities/areas of the Capsule Contractor, pertinent to Planetary Quarantine:

a. Facility Certification and Control

b. Design Review

c. Assembly, Inspection, and Test

d. Material Control

e. Assay

f. Decontamination and Sterilization

g. Documentation

The above activities will be covered in detail in the Quality Assurance Plan.

Upon completion of terminal sterilization, the Quality Assurance Manager will certify to the Project Manager that the Lander Hardware has met quality assurance requirements.

1.2 GENERAL BACKGROUND

Currently (September 1968), only dry heat has been accepted by NASA for the sterilization of spacecraft designed to enter planetary atmospheres. In order to achieve such heat sterilization, a range of time-temperature relations are being established, which, when satisfied, will provide assurance that the number of viable microorganism on the spacecraft has been reduced to an acceptable level. Table 1-1 shows typical sterilization cycles. The effectiveness of such a process presupposes that the number of viable microorganisms on the spacecraft before the heat sterilization treatment is below a certain level. It therefore becomes necessary to perform all spacecraft manufacturing, assembly and checkout functions in such a manner as to provide positive controls, measures and documentation to verify the microbiological burden levels before terminal sterilization.

Table 1-1. Typical Sterilization Cycles

Temperature (°C)	Sterilization Time (hr)	D Value* (hr)
160	3	0.21
155	4	0.31
150	6	0.46
145	9	0.73
140	14	1.1
135	22	1.8
130	34	2.8
125	53	4.4
120	84	7.0
115	132	11.0
110	210	17.5
105	336	28.0

*D-value is an abbreviation for Decimal Reduction Time which is the time required, at a given temperature, to destroy 90% of a biological population.

Sterility of the spacecraft as a result of the terminal sterilization process can be certified by inference only, since verification of the time and temperature and other parameters during such a process requires adequate control and monitoring of such activities. The role of Quality Assurance in the carrying out of such activities through in-process analysis and inspection, tests, documentation, reports and procedures is self-evident.

Although NASA Policy Directives (Ref. 1-2, 3) do not specify the methods of accomplishment of the biological burden on the spacecraft, current guidelines consider that:

a. The lander will be assembled in bioclean rooms at specified levels of assembly.

b. The landing assembly will be subjected to an approved sterilization procedure.

c. The landing assembly will be enclosed in a bacteriological barrier to maintain cleanliness and sterility. After sterilization, the enclosure will not be opened within any portion of the earth's atmosphere which might recontaminate the landing assembly.

The last item may be modified by NASA in the future to permit insertion of otherwise sterilized items which could not withstand the temperatures applied to the lander during terminal sterilization. Propellants, and experiments currently are some items that fall in this category. Development work is currently sponsored by NASA to investigate sterile assembly and sterile insertion (Ref. 1-4, 1-5). However, until specifically permitted by NASA, the above techniques shall be considered as developmental, only. Reference 1-6 presents a philosophical discussion of planetary quarantine and sterilization requirements from the near past to the present and summarizes current NASA thinking.

Reference 1-7, while not professing to represent current NASA policy or thinking, represents an excellent summary of the current state of the art in sterilization.

1.3 PLANETARY QUARANTINE

1.3.1 POLICY

By international agreement it has been decided to take all necessary steps to prevent the contamination of the planets with viable earth organisms. On December 19, 1966, the United Nations General Assembly unanimously adopted a "Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and other Celestial Bodies." Article IX of that treaty states that" ... shall pursue studies of outer space including the moon and other celestial bodies, and conduct exploration of them so as to avoid their harmful contamination..." NASA has issued policy directives which govern United States actions with respect to planetary contamination.

NASA Policy Directive NPD 8020.7 (Ref. 1-2) deals with the basic policy and responsibilities for implementation of NASA requirements for certification of the biological loading on outbound spacecraft. NASA Policy Directive NPD 8020.10 (Ref. 1-3) deals more specifically with biological contamination control of outbound planetary spacecraft.

The mere fact of the launch of a planetary spacecraft from earth implies the acceptance of a chance, no matter how small, for planetary contamination. Many attempts have been made to specify this chance numerically. In 1964, COSPAR adopted a resolution which accepted the interim objectives of the probability that a single viable organism remaining on a planetary landing spacecraft is less than 10^{-4} and the probability limit for accidental impact by nonsterilized flyby or orbiting spacecraft is 3×10^{-5} or less.

At the 1966 COSPAR meeting, a proposal was made by the United States delegation to change these limits to a 10^{-3} probability of contamination during the period of planetary exploration. The specific breakdown between probabilities of contamination for lander and orbiter is to be resolved by system design in each individual case. This resolution is currently under advisement by COSPAR. References 1-6 and 1-7 discuss this in detail. At the 1967 COSPAR meeting, these allocations were again discussed (Ref. 1-12).

NASA Policy Directive NPD 8020.10 (Ref. 1-3) states that the probability of 1×10^{-3} for planetary contamination shall be used as the guiding criterion. This became effective September 6, 1967, and represents current NASA Policy. In order to implement this policy, a mathematical model has been developed, which defines the basic formula for evaluating the planetary contamination probability by a landing spacecraft. The elaboration of the formula and the definitions involved are presented in Ref. 1-1.

1.3.2 REQUIREMENTS

NASA has issued Standards for Clean Rooms and Work Stations for the Microbially Controlled Environment (Ref. 1-8) which define the environmental controls to be used in the fabrication, test and launch environment of spacecraft subject to planetary quarantine and a section on Operational Guidelines which specifies the requirements for the dress and behavior of personnel in such facilities. This document supplements the Design Criteria and Construction Standards (Ref. 1-9) with respect to the design and construction of clean rooms and work stations for the microbially controlled environment.

In August 1967, NASA published the "NASA Standard Procedures for the Microbiological Examination of Space Hardware" (Ref. 1-10). It specifies methods, procedures and equipment to be used for the microbiological examination of spacecraft hardware and related items.

NASA has issued a basic policy document, (Ref. 1-2) as well as a specific policy document (Ref. 1-3) which relate the policy, responsibility and certification of the biological loading on outbound planetary spacecraft.

Although only dry heat has been approved by NASA for the sterilization of planetary landers, radiation and gaseous sterilization may be used for sterilization of heat-sensitive items and for sterile repair and insertion if specific and individual authorizations are obtained from the Planetary Quarantine Officer. The 12 heat cycles listed in Table 1-1, are examples of typical requirements. The D values shown in the table are based on heterogeneous mesophilic bacterial spores in soil. The specified cycles will reduce the bacterial population by 12 decades; i.e., from 10^{8} to 10^{-4} and are shown for example only. Work is in progress to specify D values for spores located in buried, mated, or surface regions.

The following are conservative values that must be used until further data becomes available.

D_{125C} (buried) = 5.0 hours

D_{125C} (Mated) = 0.3 ÷ 4.4 hours (depending on moisture imperviousness)

D_{125C} (surface) = 0.3 hour (in 40% R.H. equivalent)

*Z (buried) = $20.7^{\circ}C$

Z (mated) = $20.7^{\circ}C$

Z (surface) = $20.7^{\circ}C$

*Z-value is the change in temperature required to produce a factor of 10 change in a given D-value.

Work performed recently has shown that the bioclean assembly of planetary spacecraft in laminar flow clean rooms results in far lower contamination levels than 10^8, with some reported estimates as low as 10^5. Work performed on this contract has indicated that local protection of spacecraft hardware, when handled in non-cleanroom areas, can result in contamination levels in the 10^6 range (Ref. 1-17). Other investigations have noted similar results. The design of terminal sterilization cycles will be based on the estimated number of heat resistant organisms known to be on the planetary lander. The sterilization effect of the heatup and cooldown, as well as location, will be used in designing heating cycles. Decontamination, i.e., a reduction in microbial population without complete sterilization, may be achieved either by a shortened heat cycle or by the ethylene oxide (ETO) treatment. Development of an ETO decontamination treatment is currently in a state of flux. It is recommended that the latest NASA approved procedure be obtained before use.

1.3.3 PLANETARY QUARANTINE MATHEMATICAL MODEL

Planetary Quarantine utilizes mathematical models to establish the interrelationship of the principal parameters contributing to the probability that a planet will be contaminated. To illustrate this, the following basic formulas excerpted from Reference 1-1 are provided.

The basic formulas for planetary contamination is given by Equation 1-1, which defines contamination probabilities for landing and nonlanding missions. Equations 1-2 through 1-4 expand and detail the factors of Equation 1-1.

$$P_c = NP(N) + N'P(N') \qquad (1-1)$$

Equation 2-1 is an approximation of standard probability relationships based on the fact that in the present context, P_c is much less than unity and that, necessarily, P(N), P(N') are smaller than P_c. Also, as noted in the definitions, probabilities of contamination due to a flight vehicle are averages for the category of vehicles under consideration.

The complexity of planetary landing vehicles may lead to a distinction between contamination located in different regions of the spacecraft, each requiring separate consideration of the events contributing to the total probability of contamination by the lander. A suitable framework for this purpose is provided by Equation 1-2, provided the probability of landing is taken as unity.

$$P(N) = \sum_{j=i}^{j=m} \left[P(h) \cdot P(r) \cdot P(g) \right] j \qquad (1\text{-}2)$$

It may be assumed that contamination is segregated into three categories:

a. Buried, or internal to material to materials and components (to be denoted by the subscript b)

b. Occluded between mating surfaces (to be denoted by the subscript m)

c. Contamination on open surfaces (to be denoted by the subscript s)

Three independent contamination events would thus be considered corresponding to the above. Equation 1-2 can then be expressed explicitly as

$$\begin{aligned} P(h) = {} & P(n \geq 1)b \;.\; P(r)b \;.\; P(g)b \\ & + P(n \geq 1)m \;.\; P(r)m \;.\; P(g)m \\ & + P(n \geq 1)s \;.\; P(r)s \;.\; P(g)s \end{aligned} \qquad (1\text{-}3)$$

Thus, P(h) is, in each case the probability of a viable organism remaining after sterilization in the three regions considered. Different probabilities of release from buried, mated, and surface contamination are possible in this formulation and, if appropriate, a similar distinction can be made for probabilities of growth and spreading.

For the case of unsterilized vehicles, including that of fly-by missions, planetary contamination may be due to a number of contamination sources. P(N') may be evaluated from

$$P(N') = \sum_{i=1}^{i=k} P(h') \cdot P(r') \cdot P(g') \qquad (1\text{-}4)$$

where k is the total number of i independent contamination sources. (Sources which are not independent would be viewed as jointly constituting a single source.)

The most difficult part of the task of defining input parameters, is the selection of quantitative values, since many of these are based on inference, estimates or sometime just educated guessing. Continuing research and flight vehicle data have been increasing the amount of factual information available. For this reason, there will be continuing updating and revision of such parameters. Currently, the following parameters values are recommended for use with the above equations.

$P_c = 1 \times 10^{-3}$

$N = 50$

$P(r) =$ to be established for each j source

$P(g) = 1 \times 10^{-3} = P(g)_b = P(g)_m = P(g)_s$

$N' = 50$

$P(h') =$ to be established for each i source

$P(r') =$ to be established for each i source

$P(g') = 1 \times 10^{-3}$

The spacecraft sterilization requirement shall be based on the value of $P(n \geq 1)$. The allocation of probability of contamination to the 1973 mission shall be less than 1×10^{-5}.

P_c for both sterilized and unsterilized vehicles shall be 1×10^{-3}.

DEFINITIONS AND NOMENCLATURE FOR PLANETARY QUARANTINE MODELS

T	Time period of unmanned biological exploration (years) during which contamination is to be prevented.
P_c	Probability that, during the time period T, the planet under consideration will be contaminated so as to constitute a significant detriment to the intended program of biological exploration.
N	Number of vehicles intended to land or impact on the planet during the time-period T.
$P(N)$	Average probability that any one of the N landing vehicles will cause planetary contamination.
N'	Number of vehicles in the planetary exploration program which are not intended to land on the planet during the time-period T. This category of flight vehicles include orbiters, flyby missions, and the carriers of landing vehicles.
$P(N')$	Average probability that any one of the N' nonlanding vehicles will cause planetary contamination.
n	Number of viable microorganisms present.
n_o	Initial population of viable microorganisms, e.g., at initiation of the sterilization process.
$P(n \geq 1)$ $P(n=1)$	Probability that one or more or exactly one viable microorganism will be present.
h	Transfer of viable microorganisms to the planet so as to create a contamination hazard. Note: this is a generalized symbol for all contamination events to be considered for a flight vehicle, each event requiring assessment of probabilities of release, growth, and spreading.
$P(h)$	Probability that the event h will occur.
r	Release onto the planet surface or into its atmosphere, organisms which have survived sterilization, given that they have been transferred to the planet.
$P(r)$	Probability that the event r will occur. Note: P(r) is the conditional probability or release, given that the event h has occurred.

DEFINITIONS AND NOMENCLATURE FOR PLANETARY QUARANTINE MODELS (Cont)

r'	Release onto the planet surface or into its atmosphere, organism(s) not subjected to sterilization, given that they have been transferred to the planet.
$P(r')$	Probability that the event r' will occur. Note: $P(r')$ is the conditional probability of release, given that the event h' has occurred.
g	Growth and spreading on the planet surface or into its atmosphere of terrestrial microorganisms which survived a sterilization process, given that events h and r have occurred.
$P(g)$	Probability that the event g will occur. Note: $P(g)$ is the conditional probability of growth and spreading, given that events h and r have occurred.
g'	Growth and spreading on the planet surface or in its atmosphere of terrestrial microorganisms which had not been subjected to sterilization, given that events h' and r' have occurred.
$P(g')$	Probability that the event g' will occur. Note: $P(g')$ is a conditional probability of growth and spreading, given that events h' and r' have occurred.

1.4 TRAINING PROGRAMS

1.4.1 INTRODUCTION

The basically different background of physical sciences oriented personnel in relation to the life-sciences requirements of the planetary quarantine and sterilization programs, requires personnel training and orientation to assure the success of such programs. Such training is particularly desirable for quality assurance personnel because of their surveillance and audit functions of microbiological and related procedures. As a rule, the following types of personnel should be required to attend a training course before starting work on a planetary spacecraft to be sterilized by heating in accordance with NASA requirements.

a. Senior engineering personnel

b. Program office personnel

c. Design engineers

d. Quality assurance personnel

e. Checkout and test engineers

f. Assembly and test technicians

In general, all personnel who will come in physical contact with the spacecraft or any of its subsystems must, as a minimum receive an orientation lecture. Although the degree of training and the selection of personnel required to take such training rests with the program office and planetary quarantine officer, this section of this manual will outline the responsibilities of the quality assurance organization with respect to such training programs.

1.4.2 RESPONSIBILITIES

Quality assurance participation in planetary quarantine and sterilization related training program is three-fold, as follows:

a. Administration of training programs in conjunction with the planetary quarantine officer, microbiologist, engineering and other functions

b. Certification and recertification (as well as decertification) of personnel requiring access to flight hardware and vehicles

c. Participation in training courses as a prospective planetary program member

These activities will be discussed separately.

1.4.2.1 Training Program Administration

The need for a continuous and comprehensive training program for personnel engaged in a planetary spacecraft program is consistent with planetary quarantine requirements. Although the administration of such a series of programs can rest with one of several groups within the framework of a project organization, it will be assumed here that Quality Assurance has been assigned this function. This requires extensive interface activities with other groups, since the following specialties must be represented in such a program as task leaders in lectures or discussions.

a. Microbiology
b. Contamination Control
c. Project Engineering
d. Sterilization
e. Planetary Quarantine
f. Quality Assurance
g. Design Engineering
h. Assembly, Test & Checkout

1.4.2.2 Certification

Personnel who successfully complete the course or lecture series will have their names entered on a qualification list, which will also be a part of the Data Bank. Thus, certification will be a requirement for access to flight hardware. The amount of training will be determined by the Planetary Quarantine Officer or his designated Sterility Control group.

Generally, the amount of training is directly related to the probability of the individual's opportunity to compromise sterility of the spacecraft system.

Decertification will be initiated when:

a. A person previously certified leaves the project for a period of time to be specified by the sterility control group

b. A person has committed sterility or contamination control violations, (subject to definitions by sterility control group)

c. Procedures and/or policy change sufficiently to require retraining

d. Employment terminates

Statistical approaches performed by industrial organizations have shown that "skill retention or problem awareness" does not maintain a constant level with respect to time. It is a human trait that routine procedures breed carelessness. For such reasons, recertification of personnel is required. Although the periodicity of recertification requirements can vary with the type of personnel involved, a definite plan needs to be established. As a minimum, personnel need a review session monthly. Such review sessions can indicate previously unknown or neglected problem areas, point out errors or omissions and otherwise serve as a feedback system.

1.4.2.3 Training Courses

The need for quality assurance personnel to participate in specialized training courses along with other project personnel is self-evident. The types of courses are:

a. Quality Assurance Management Courses

b. Planetary Quarantine and Sterility Control

A formal Quality Assurance Management indoctrination and training program needs to be established for personnel having a direct bearing on product quality. Such a program should center on the explanation and understanding of management controls that need to be implemented to ensure product quality. The course material should follow the traditional business cycle of a product:

a. Program Requirements and Integration

b. Design and Development

c. Procurement Control

d. Manufacturing and Related Process Controls

e. Testing Array and Equipment Calibration

f. Assembly Manufacture and Checkout

g. Systems Acceptance and Field Interface

h. Field Control and Information Feedback

i. Nonconforming Materials, Control of

j. Data Evaluation and Cost Analysis

These courses should first be directed to those personnel within the Quality Assurance Operation having an immediate need. The course should then permeate throughout the Quality Assurance Operation and allied operations, e.g., Engineering and Manufacturing.

Sterilization oriented indoctrination and training programs need to be established for personnel having responsibility in product quality or who will be in direct contact with prime hardware. The course material shall consist of the following:

a. Planetary Quarantine Requirements

b. Assembly, Test, Checkout, Sterilization Cycle of Spacecraft

c. Microbiological Contamination Control

d. Microbiological Assay Procedures

e. Documentation and Inspection Requirements

f. Sterility Control Policies

g. Control of Sterility Violations

h. Personal habits and Behavior in Work Areas

Although the course material represents an outline rather than a rigid requirement, it indicates the subjects to be covered. As a minimum, all personnel entering microbial contamination controlled work areas should be cognizant of Items a and h. For QA personnel monitoring microbiological activity, additional training is required.

In the case of visitors, reading of a summary sheet covering Items a and h and acknowledgement by signature, appears adequate.

1.4.3 TRAINING AIDS

1.4.3.1 Training Courses Available

Table 1-2 shows a partial list of training courses in microbiological contamination control, suitable for engineers.

1.4.3.2 Visual Aids

Table 1-3 shows a partial listing of films available that can serve as an introduction in microbiology, exobiology and spacecraft sterilization.

1.4.3.3 Publications

Sources of background material for the field of microbiology and spacecraft sterilization are provided in a number of bibliographies published under NASA sponsorship. A partial listing of these bibliographies is shown in Table 1-4.

Table 1-2. Partial List of Training Courses

Course	Sponsor	Length	Frequency	Location
Environmental Microbiology for Engineers	NASA University of Minnesota	One Week	As required by NASA and by demand	Various Locations (by demand)
Bio-Space Technology Training Program	NASA and University of Virginia	Two Weeks	Yearly, usually during the summer	Wallops Island, Virginia
Microbiological Analysis, Sterile Filtration and Clinical Techniques	Millipore Filter Corporation	One Day	Yearly at given location	Various Major Cities
Audio-Tutorial Bacteriology Course	Kansas State Teachers College	Semester	-	Emporia, Kansas
Clean Packaging	Clean Room Products, Inc.	One Day	By Request	Manufacturer's Plant or Farmingdale, N. Y.
Various special topics of Biological and Sterilization interest	United States Public Health Service, Communicable Disease Center, Savannah, Georgia	As recuired (from one day to two weeks)	On Demand	Savannah, Georgia
Contamination Control	Specialty Training Division, Specialty Convection, Inc.	2 days to one week	On Demand	Monrovia California or at Manufacturer's Plant

Cost	Content Summary	Contact for Information	Remarks
No charge	Directed primarily at Spacecraft Sterilization and Planetary Quarantine Problems.	Planetary Quarantine Officer, Code SB, NASA, Washington, D.C. 20546	This is the primary course for the space-craft sterilization program.
No charge	Known space environment, trajectory and orbital considerations, performance summary and usage of existing rocket boosters, biological data handling and instruments, introduction to launch range facilities and biospace flight facilities.	Director, Conference and Institute, University of Virginia, School of General Studies, P.O. Box 3697, Charlottesville, Virginia 22903	Limited participation. NASA approval required.
No charge	Physical and chemical characteristics of filters, sterile filtration, preparation and sterilization of equipment, filtration, sterility testing, microbiological analysis of H_2O, and analytical microbial techniques	Millipore Filter Corp. Bedford, Mass. 01736 Attn: Sales Manager	Requires some experience.
-	General and basic bacteriology.	Dr. Ted E. Surdy Kansas State Teachers College, Emporia, Kansas	This is a course for Kansas State Teachers College students. For availability of tapes, contact Dr. Surdy. Requires laboratory facilities.
-	Complete guide to clean packaging, theory, choice of materials, cleaning procedures, and state-of-the-art.	President, Clean Room Products, 55 Central Ave. Farmingdale, N.Y. 11735	Applicable to both biological and non-viable contamination control packaging.
No charge	These courses cover a wide range of special topics and are adapted to meet needs of the time and changes in the areas of interest to the National Welfare		
$180 per person	Complete clean room discipline course. Theory operations and practice.	President, Specialty Training Division, 120 Taylor St., Monrovia, California.	Course adapted to use requirements. (NASA cooperation)

Table 1-3. Partial Listing of Films

Title	Contact for Information	Length	Sound
1. Selected Films and Slides	A list and abstracts are available from American Society for Microbiology, 115 Huron View Boulevard, Ann Arbor, Michigan 48103.		
2. Decontamination of Space Vehicles HQ-35, (1961)	National Aeronautics and Space Administration, Educational Audio-Visual Branch, Code AFEE-3, Washington, D.C. 20546	18 min	X
3. Life on Other Planets, HQ-34, (1961)	National Aeronautics and Space Administration, Educational Audio-Visual Branch, Code AFEE-3, Washington, D.C. 20546	21 min	X
4. Chemical Disinfection, 16mm, M-816 (1964)	Public Health Service Audio-visual Facility, Chamblee, Georgia 30065, Attn: Film Distribution	30 min	X
5. Sterilization Problems and Techniques, 16 mm, M-736 (1963)	Public Health Service Audio-visual Facility, Chamblee, Georgia 30065, Attn: Film Distribution	30 min	X
6. Basic Biology of Bacteria, 35 mm, 5-174 (1950)	Public Health Service Audio-visual Facility, Chamblee, Georgia 30065, Attn: Film Distribution	56 Frames	X
7. The Growth of Bacteria, Yeasts and Molds (1933)	American Society for Microbiology, 115 Huron View Boulevard, Ann Arbor, Michigan 48103.	22 min	No
8. Air Sampling for Microbiological Particulates, 16mm, M-926 (1965)	Public Health Service Audio-visual Facility, Chamblee, Georgia 30065, Attn: Film Distribution	11 min	X
9. Surface Sampling for Microorganisms (Rodac Plates) (1965)	Public Health Service Audio-visual Facility Chamblee, Georgia 30065, Attn: Film Distribution	8 min	X
10. Surface Sampling for Microorganisms 16 mm, M-925	Public Health Service Audio-visual Facility Chamblee, Georgia 30065, Attn: Film Distribution	5 min	X

Summary
Basic microbiology characteristics of bacteria, fungi, viruses Dr. C.R. Phillips and Mr. R.K Hoffman of Ft. Detrick, Maryland discuss the biological problems and the needs for the decontamination of space vehicles. They show different methods of achieving decontamination. Dr. J. Lederberg (Stanford University) discusses the possibility of life existing on other planets. He tells of the various ways that life could have been introduced, and he describes the methods for detecting and investigating the problem. A filmed lecture by Dr. Earle H. Spaulding, Chairman, Department of Microbiology, Temple University School of Medicine, Philadelphia, Pa., on chemical disinfection in hospital practices. Definition factors involved in disinfection and recommendations are covered. A filmed lecture by Dr. J.C. Kelsey, Director, Disinfection Reference Laboratory, Central Public Health Laboratory, London, on sterilization in hospital practice. Definitions, use of dry and moist heat (steam) and chemical and radiological sterilization are discussed. An introduction to bacteriology. Explains the characteristics of bacteria, differences in types, feeding and multiplication and control through boiling, freezing and pickling. Elementary explanation for nonprofessional audiences. Shows reproduction by fission, budding and branching in bacteria, yeast and molds. Illustrates colony development, pigment production. Vacuole formation and protoplasmic streaming. Shows proper techniques and procedures for sampling airborne bacteria in hospitals using Reyniers and TDL Samplers. Illustrates reasons for airborne sampling, operation of the Reyniers sampler, operation of TDL sampler and counting bacterial colonies. Teaches proper techniques and procedures of surface sampling for bacteria in hospitals, using Rodac Plates. Gives reasons for surface sampling, preparation of the agar sampling plates, description of the random and geometric grid sampling methods, and the counting and reporting of colonies. Shows proper techniques and procedures of surface sampling for bacteria in hospitals using the swab and template. Gives reasons for surface sampling, techniques of sampling on flat and irregular surfaces processing swabs and rinse liquids, counting of microbial colonies and interpretation of results.

Table 1-4. Partial Listing of Bibliographies

Title	Source	Remarks
A Selected Bibliography from the Literature Retrieval System; Space Biology Branch, X-624-67-564 (November 1967)	NASA-Goddard Space Flight Center Greenbelt, Md. Space Biology Branch Code 624	326 References
Bibliography on Planetary Quarantine - Vol. I Policy, (D.E. Wright, November 1967)	Biological Sciences Communication Project, George Washington University, Washington, D.C. 20036	123 references on policy, sterilization related requirements, conference proceedings and background information items on NASA position.
Bibliography on Planetary Quarantine - Vol II, Environmental Microbiology, (D.E. Wright, November 1967)	Biological Sciences Communication Project, George Washington University, Washington, D.C. 20036	359 references and citations involving microbial growth, detection, identification and monitoring throughout spacecraft fabrication.
Bibliography on Planetary Quarantine - Vol III, Engineering Parameters, (D.E. Wright, November 1967)	Biological Sciences Communication Project, George Washington University, Washington, D.C. 20036	251 references on development and testing of spacecraft components and sterilization and decontamination procedures.

1.4.3.4 NASA Publication, "Spacecraft Sterilization Technology"

This presents the best compilation of sterilization state of art as of 1966. It is based on the NASA-sponsored First National Conference on Spacecraft Sterilization Technology held at Pasadena, California, in November 1965 (Reference 1-16).

1.5 DATA BANK

The execution of a meaningful quality program which includes mathematical modelling as well traceability capability requires a data bank. Such a data bank would be a repository for all quality, checkout, contamination and sterilization data for all spacecraft components, systems and assemblies up and including to canister mating and terminal sterilization. This data bank differs from conventional spacecraft data banks in that it includes the additional data due to sterilization, planetary quarantine and biological burden accumulation requirements.

The need for a data bank, however, extends beyond the requirements of the Quality Assurance program only. It was considered a prime requirement of the Voyager Planetary Quarantine Plan (Ref. 1-13) by being considered a part of Voyager Data Management System. The following excerpts from Reference 1-13 will illustrate the type information and utilization which can be expected from a data bank in a Quality-Assurance or as a Management Plan application.

Contamination Data Bank

> "The Planetary Quarantine Contamination Data Bank, as a part of the Voyager Data Management System, will be established to satisfy a portion of the quarantine requirements. It will be used by Voyager Project and System Management, by NASA Headquarters, and by development contractors to function as follows:
>
> a. Assure that contamination and sterilization decontamination is complete and adequate.
>
> b. Assure that documentation is traceable for all affected assemblies and components.

c. Ensure applicability of sterilization processes and related specifications.

d. Implement the Planetary Quarantine Data Plan in an efficient orderly manner.

e. Make certain that identification of the sterilization data clearly establishes the identity of each component and/or assembly as the source.

f. Provide current information on short notice upon demand in order to establish or adjust predicted microbial contamination load estimated for the Capsule before terminal sterilization.

g. The Contamination Data Bank shall be the repository of all contamination and sterilization data for all equipment in Capsules to be sterilized, down to and including the piece-part level.

h. Prime contractors shall be required to maintain, for flight hardware, the same depth of contamination and sterilization data, and to provide the Voyager Data Management System with this data at specified intervals. Contamination and sterilization data requirements shall be determined during the design phases of the Project.

i. The Contamination Data Bank shall provide, under the Planetary Quarantine Chief's direction, computer-processed reports, in a predesigned format(s), on a predetermined schedule basis to a controlled distribution. Demand reporting will be handled on a case-by-case basis. Some typical types of reporting and computer usage are as follows:

   1. Recording, maintaining, and reporting assay records

   2. Developing contamination curves

   3. Determining probability of flight capsule contamination (mathematical model)

   4. Providing traceability of assemblies and components through the sterilization process (in conjunction with the Voyager Configuration Management System).

   5. Generating reports of temperature cycling times, accumulated against critical components or assemblies, to provide for prediction of possibility of additional temperature cycling degrading reliability."

In the absence of a current planetary project, these functions represent the latest contamination data bank philosophy.

1.6 REFERENCES

1-1 General Electric Co., "Biological Handbook for Engineers," Contract NAS 8-11372, Procedures Manual for Spacecraft to be Sterilized by Heating, Revised Ed. (1968).

1-2 "Outbound Spacecraft: Basic Policy Relating to Lunar and Planetary Contamination Control, "National Aeronautics and Space Administration, Publication NPD 8020.7 Washington, D. C., September 1967.

1-3 "Outbound Planetary Biological Contamination Control, Policy and Responsibility," National Aeronautics and Space Administration, Publication NPD 8020.10, Washington, D. C., September 1967.

1-4 General Electric Co., "Assembly/Sterilizer Facility Feasibility Program," Contract NAS 1-5381, Final Report, GE Document 67SD604, (1967).

1-5 Martin-Marietta Corporation, "Development and Test of a Sterile Insertion Repair Technique," Contract NAS 8-21122, Final Report MCR-67-401, (1968).

1-6 Hall, L. B., "Recent Developments in Planetary Quarantine," Development in Industrial Microbiology, Vol. 9, p. 19-29, (1968).

1-7 Craven, C. W.; Stern, J. A.; Ervine, G. F., "Planetary Quarantine and Space Vehicle Sterilization," Astronautics and Aeronautics, p. 18-48, Vol. 6, No. 8, (August 1968).

1-8 "NASA Standards for Clean Rooms and Work Stations for the Microbially Controlled Environment," National Aeronautics and Space Administration, Publication NHB 5340.2, Washington, D. C., August 1967.

1-9 "Design Criteria and Construction," Publication NPC 325-1, National Aeronautics and Space Administration, Washington, D. C., 1967.

1-10 "NASA Standard Procedures for the Microbiological Examination of Space Hardware," National Aeronautics and Space Administration, Publication NHB 5304.1, Washington, D. C., August 1967.

1-11 Hall, L. B., "NASA Requirements for the Sterilization of Spacecraft," Spacecraft Sterilization Technology, Pasadena, California, NASA SP-108, pp. 25-36, 1966.

1-12 Hall, L. B., "The Importance of Sterilization Techniques in Spacecraft," COSPAR, London, August 1967.

1-13 "Planetary Quarantine Plan - Voyager Project," Doc. 818-11-PQ001, NASA, 3rd Revision 1 June 1967.

1-14 "Space Vehicle Stage Analysis and Checkout Guidelines," NASA-MSFC Publication SR-QUAL-64-13, May 1964.

1-15 "Quality Assurance Provisions for Inspection Agencies," NPC200-1, April 1962.

1-16 "Spacecraft Sterilization Technology," National Aeronautics and Space Administration, Publication SP-108, Washington, D.C., 1966.

1-17 Fried, E., Gillis, J.R., Stahler, M.R., "Quality Assurance Requirements for Planetary Spacecraft to be Sterilized by Heating," Contract NAS 8-21139, Final Report 68SD4250, General Electric Company, Philadelphia, Pa., December 1968.

SECTION 2

QUALITY ASSURANCE PLAN

SECTION 2
QUALITY ASSURANCE PLAN

2.1 INTRODUCTION

The ability to deliver a planetary spacecraft conforming in all respects to the Planetary Quarantine as well as functional and mission requirements, requires a workable and adequate quality assurance plan. Quality can neither be inspected into a product; nor can it be added after a piece of hardware has been completed. The performance of quality assurance implies that conformance with all engineering, design, test and planetary quarantine specifications and requirements is observed, verified, documented and made retrievable and traceable. To do this, a Quality Assurance Plan must be provided, delineating the function, activities, documentation, training and organizational relation for the Quality Assurance team. Because each project or program must have a program plan specifically tailored to its end-item and organization structure, the plan outline presented herein will be limited primarily to the planetary quarantine oriented activities. Since a plan must be based on the guidelines and provisions of "Quality Program Provisions for Space Systems Contractors" (NASA Document NPC 200-2, Ref. 2-1), this outline is no exception. However, it goes beyond the requirements of Reference 2-1, to include the particular microbiology oriented aspects of the planetary quarantine requirement. In addition to the broad outline of NPC200-2, the NASA-George C. Marshall Space Flight Center Publication SR-QUAL-64-13 (Ref. 2-2) is used extensively in this manual. Specific details or procedures in the planetary quarantine cognizant areas are based on reported work by the General Electric Company (Ref. 2-4), the Jet Propulsion Laboratory (Ref. 2-5, 2-6), and on actual hardware experience in the course of a current NASA-MSFC funded program (Ref. 2-7) and other sources. Parts of the plan outline are given in this section with others in subsequent sections of the manual. This approach was taken to emphasize the planetary quarantine affected phases of the plan.

2.2 RESPONSIBILITIES

Quality Assurance responsibilities for a Planetary Spacecraft Program include, in a broad sense, the following:

a. Control of Procured Items

b. Control of Manufactured Items

c. Control of Subassembly Items

d. Control of Major and Final Assembly

e. Checkout and Test

f. Canister Mating and Sterilization

g. Spacecraft Mating and Launch Activity

h. Data System

This manual will concern itself primarily with planetary quarantine affected items although the quality assurance requirements for planetary landers include all the above in the fullest sense of quality assurance. As an example, Figure 2-1, shows the typical quality work elements as used in spacecraft programs. The major additional quality elements are concerned with the microbiological requirements as prescribed by planetary quarantine. Figure 2-2 shows a detailed example of a typical make-or-buy sequence for the procurement, fabrication and sterilization of Voyager hardware and is typical of the kind of planning required. Figure 2-3, also based on the Voyager program, illustrates general quality assurance documentation flow. It does not include the data bank, bio-assay data and other bio-burden data, because it was prepared for use with an orbiting spacecraft, which may only need to be decontaminated. It does, however, illustrate the extensive documentation required for proper control.

2.3 QUALITY ASSURANCE PLAN OUTLINE

A quality assurance plan for a mission and program must be tailored to that program and the performing organization to be functionally effective and economically acceptable. The plan outline items presented here are unique to a planetary quarantine governed program. Only highlights are presented for special requirements, because the current NASA policy details are in the process of added definition. Items customary in all spacecraft

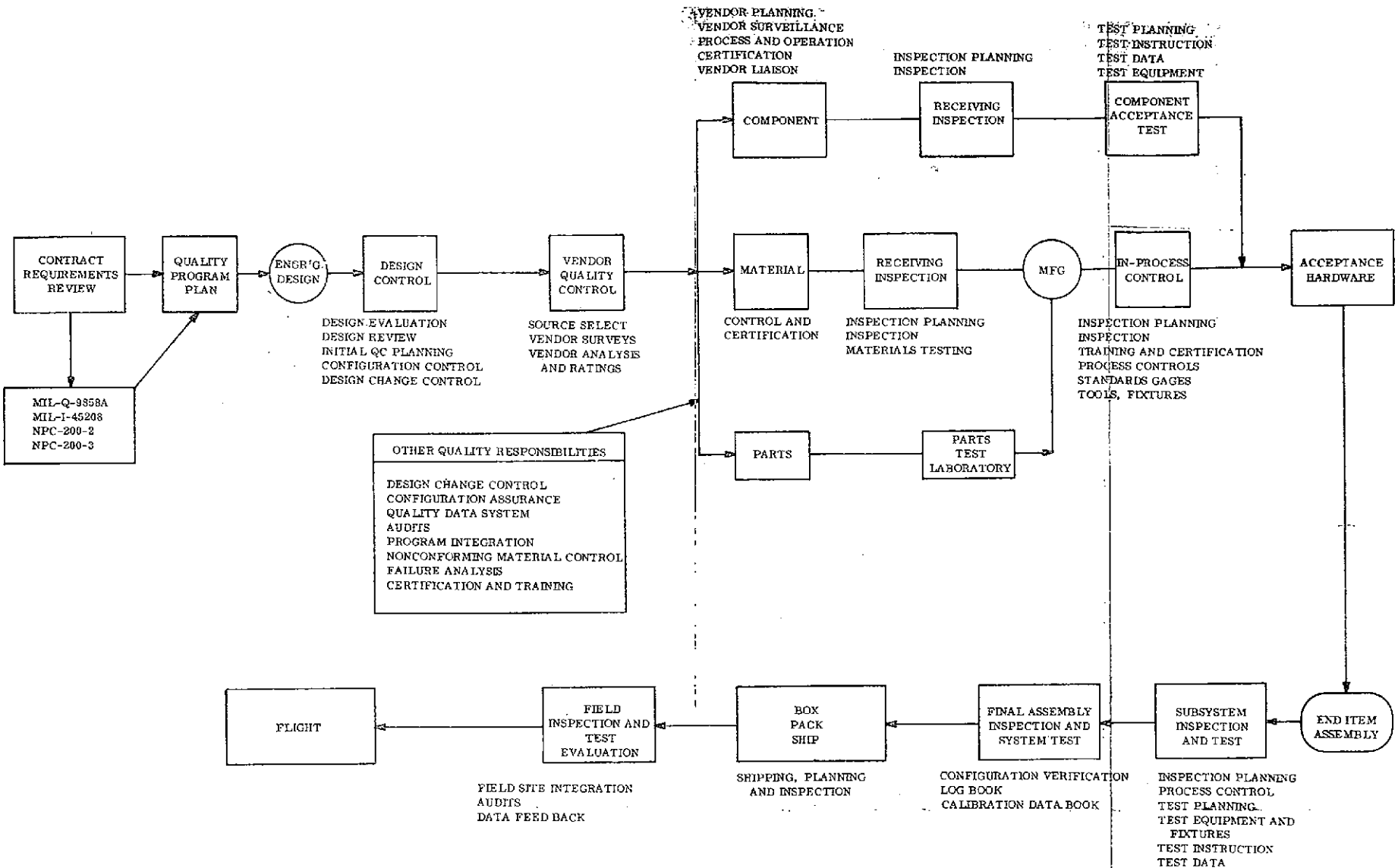
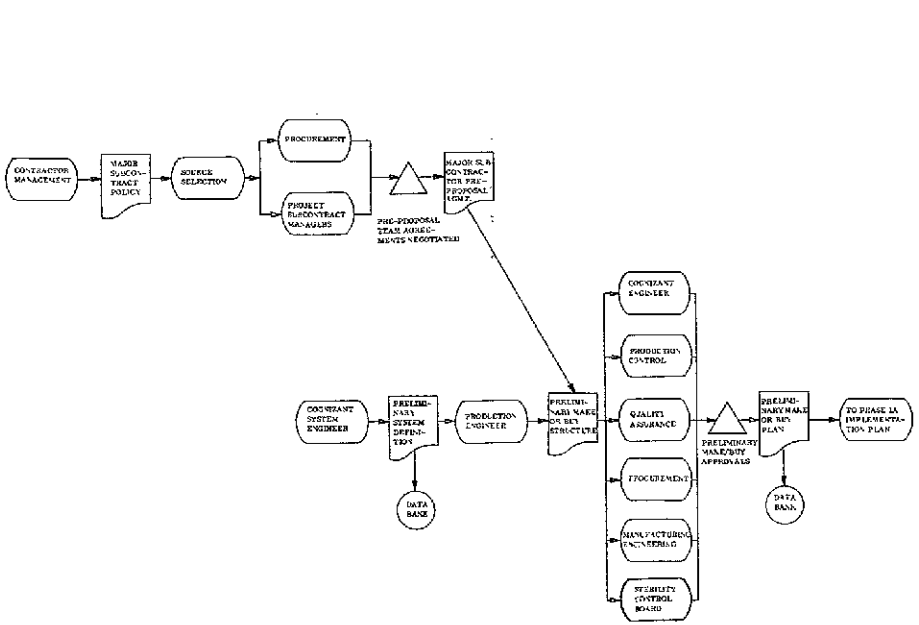
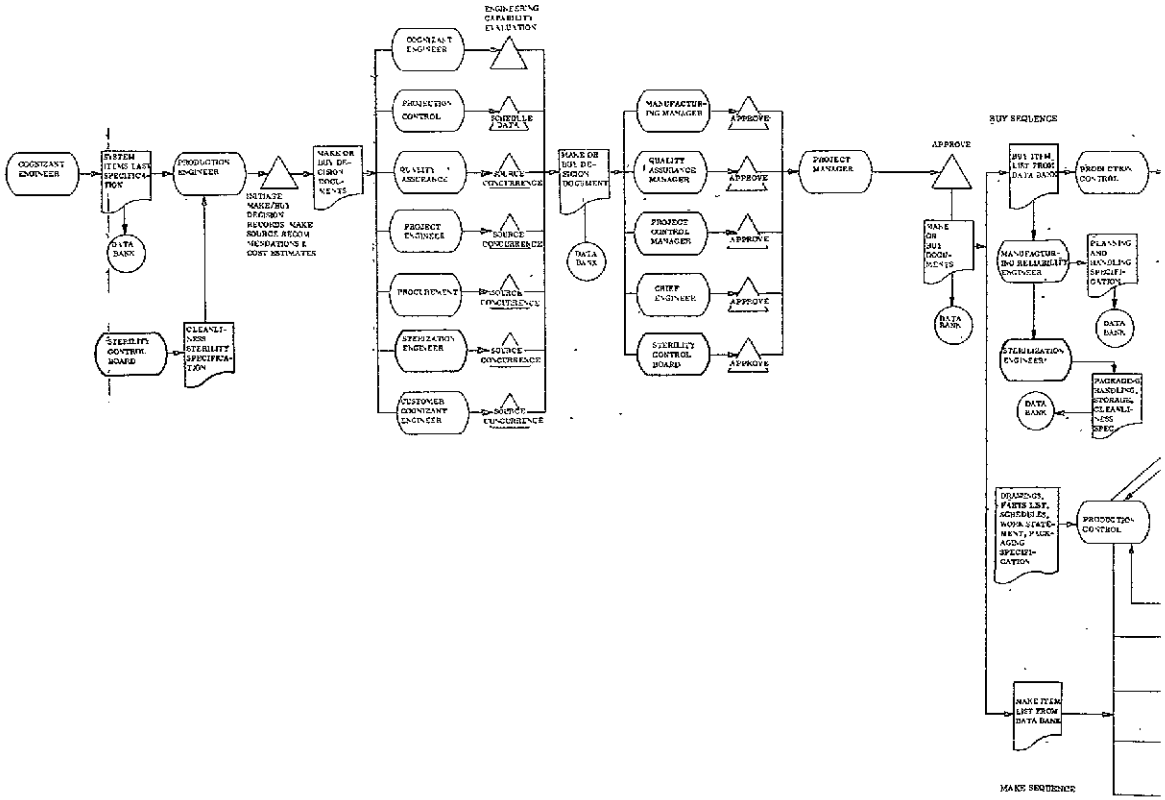


Figure 2-1. Typical Quality Work Elements

FOLDOUT FRAME 1

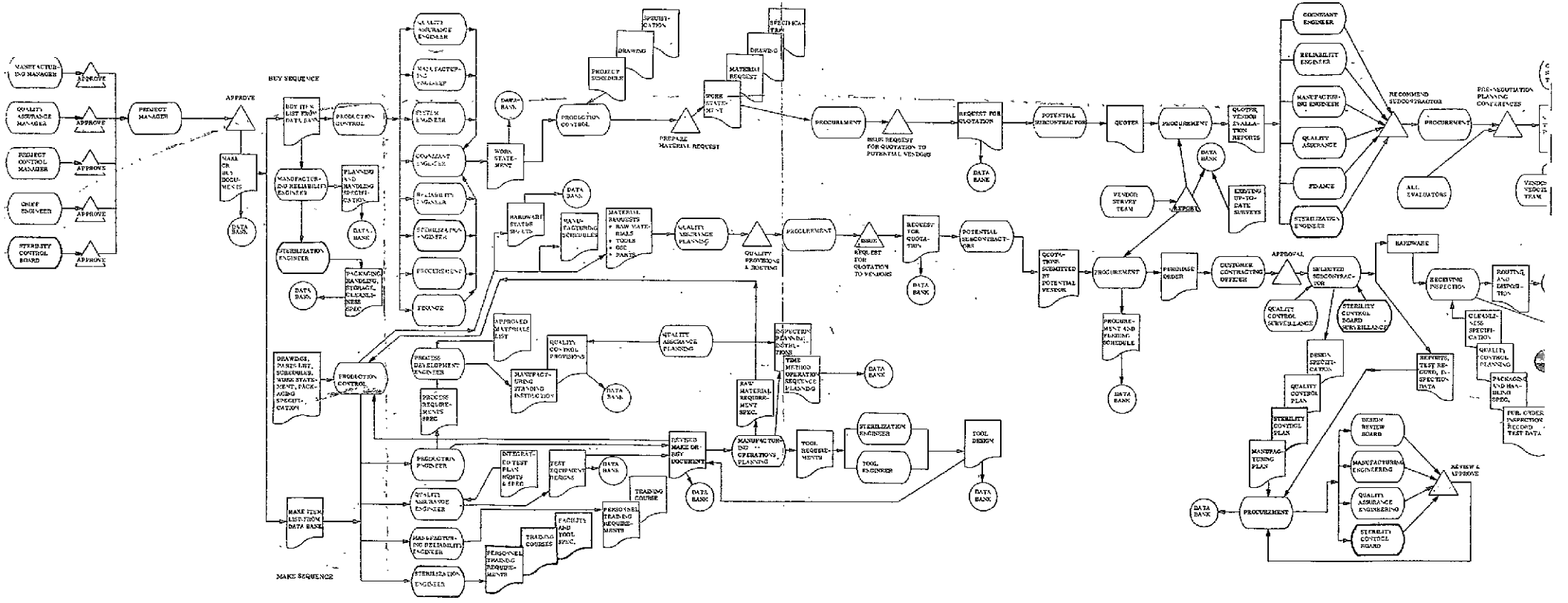
FOLDOUT FRAME 2





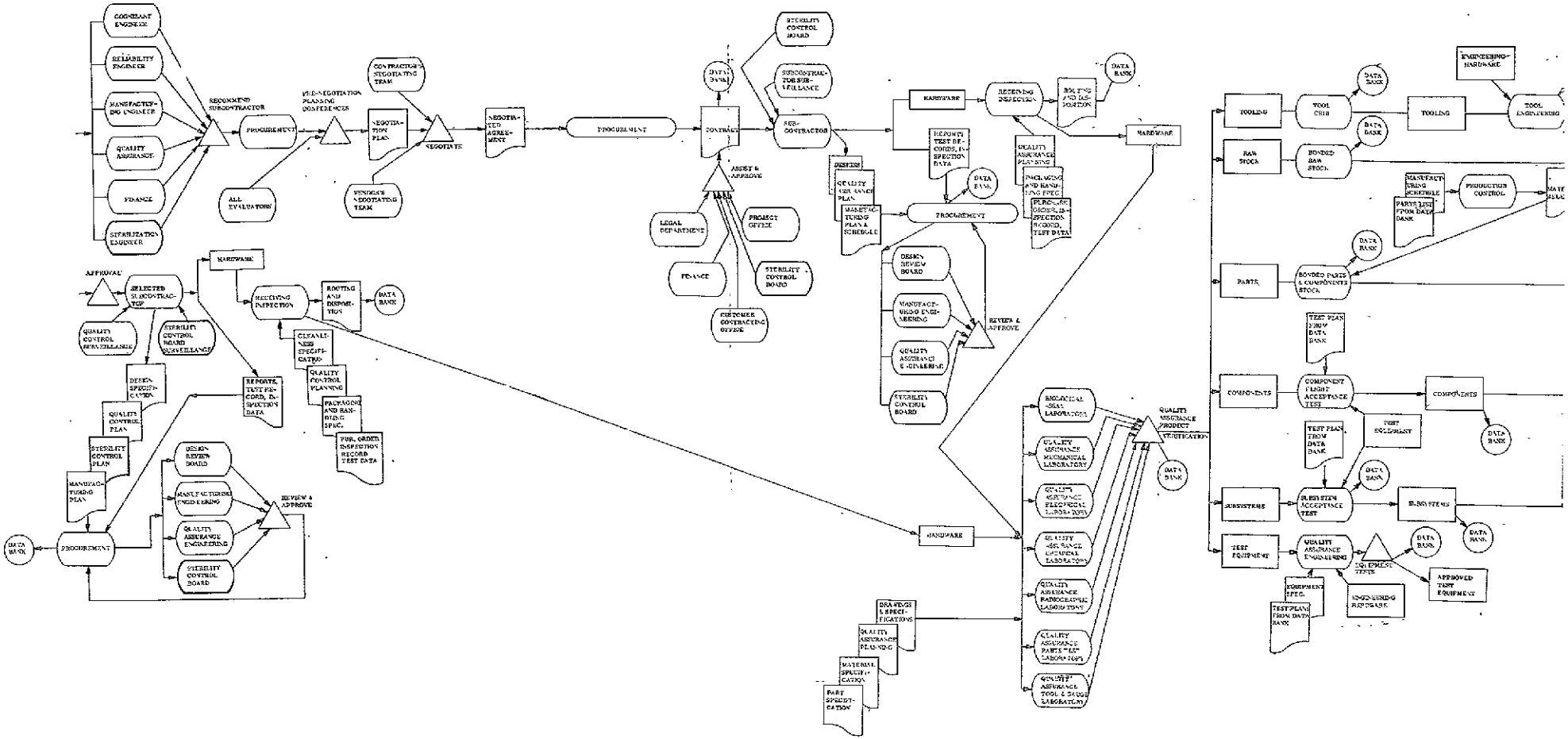
FOLDOUT FRAME 1

FOLDOUT FRAME 2



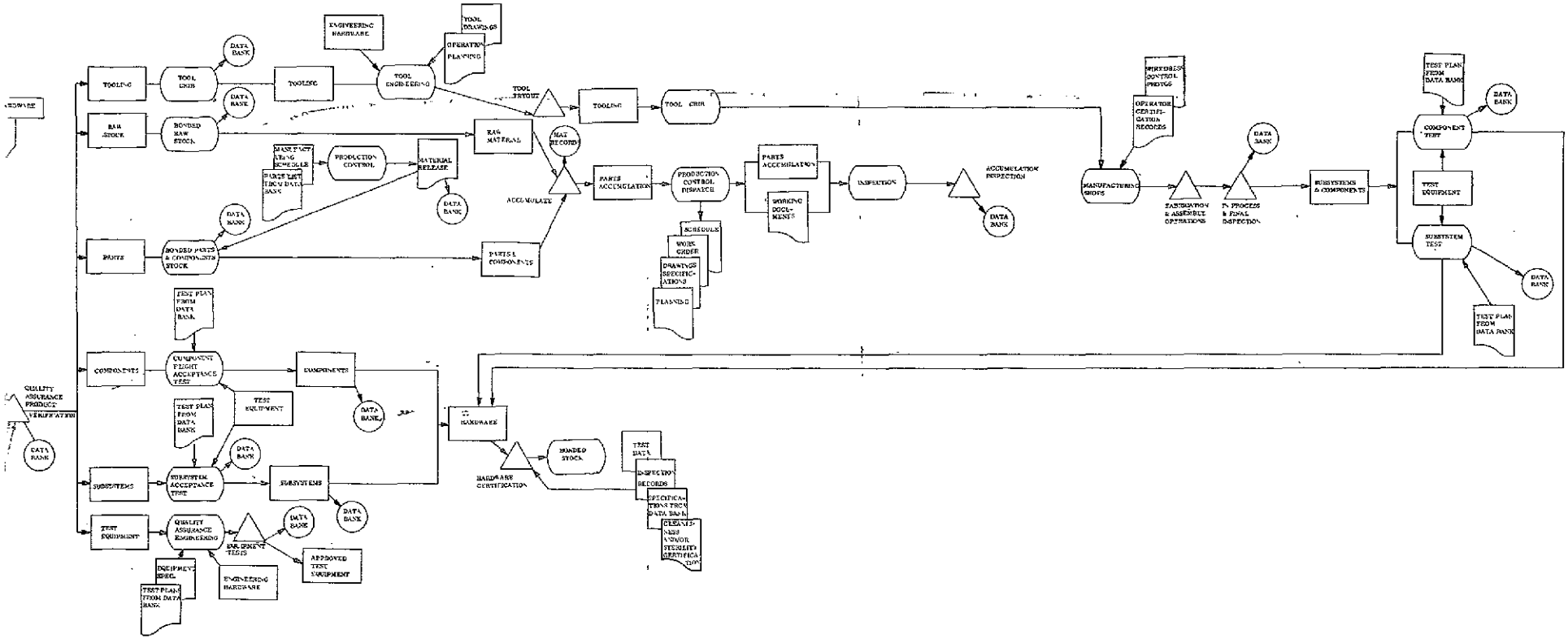
FOLDOUT FRAME 3

FOLDOUT FRAME 4



FOLDOUT FRAME 5

FOLDOUT FRAME 6



FOLDOUT FRAME

FOLDOUT FRAME

Figure 2-2. Typical Make or Buy Sequence for the Procurement, Fabrication, and Sterilization of Aerospace Hardware

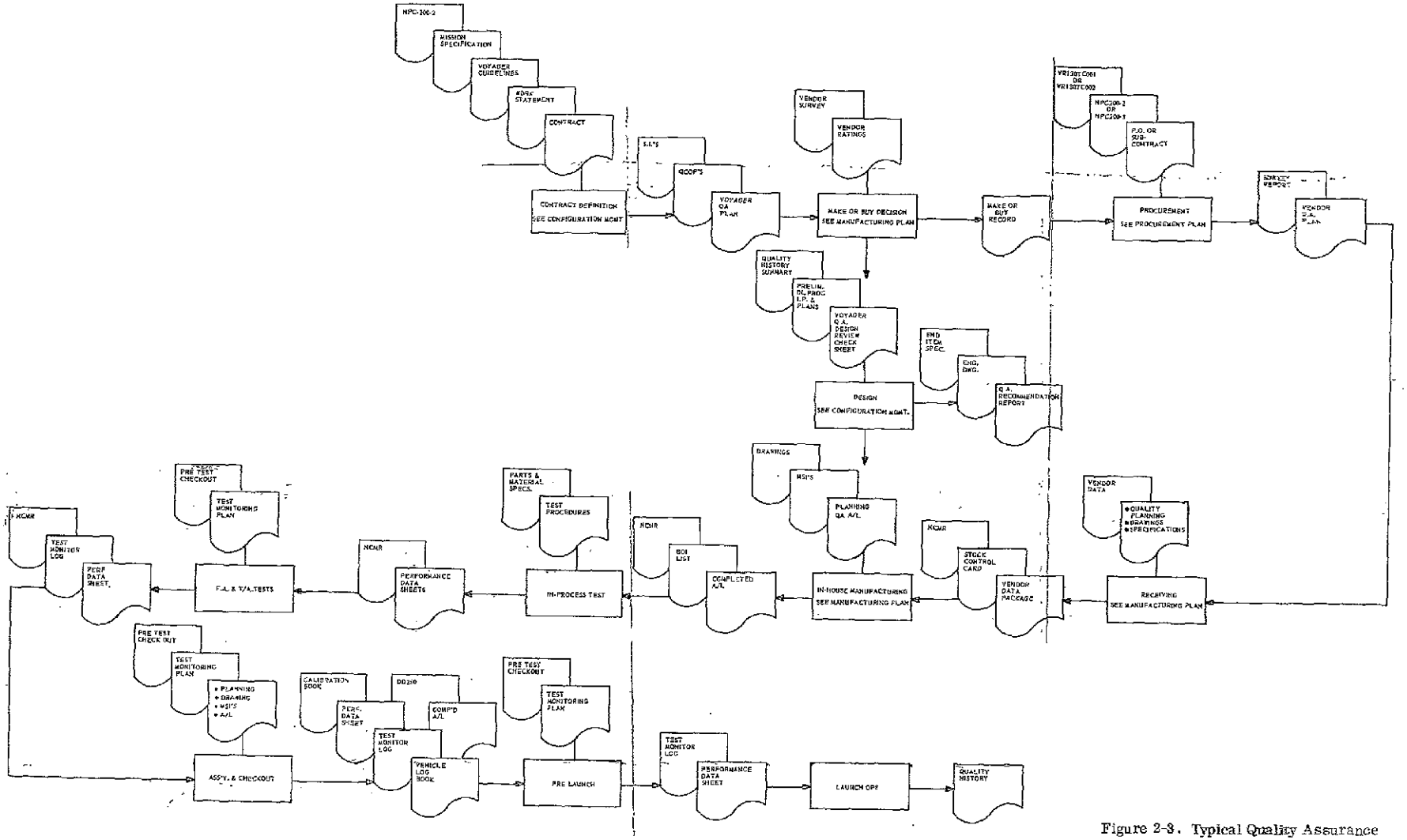


Figure 2-3. Typical Quality Assurance Documentation Flow

FOLDOUT FRAME 1

FOLDOUT FRAME 2

programs such as receiving inspection, fabrication, assembly and related procedures are covered in subsequent sections of the manual. They roughly follow the prescribed sequence of quality assurance and inspection plans as outlined in "Quality Assurance Provisions for Inspection Agencies" NPC 200-1 (Reference 2-3).

a. Receiving inspection and test

b. Qualification inspection and test

c. In-process inspection and test

d. End-item inspection and test

e. Shipping inspection

f. Storage inspection

The plan necessarily also follows the format outlined in NPC 200-2, (Reference 2-2), including Basic Requirements, organization and Management, Receiving Inspection, Fabrication, Assembly, Test, Packaging, Statistical Analysis and Audits, but not necessarily in this order.

2.3.1 ORGANIZATION

The Quality Assurance organization shall include, in addition to normally required personnel, assigned personnel from microbiology, data systems and contamination control. All such personnel shall have participated in the appropriate training courses. The size and reporting level of this organization shall be commensurate with its program management assigned responsibility.

The organization shall include the following types of personnel:

a. Quality Assurance Chief

b. Professional Quality Assurance Personnel

c. Quality Assurance Technicians

d. Assigned Personnel as required

The degree of overlap in responsibilities between Quality Assurance personnel and Microbiology Personnel, Manufacturing personnel, Facility personnel, Test personnel and other review or audit groups should be reduced by specific delineation of such responsibilities at the start of the program.

Specific examples of anticipated quality assurance activities which are introduced by planetary quarantine are:

a. Microbiological Materials Receiving Inspection

b. Microbiological Facility Certification and Monitoring

c. Visual Monitoring of Spacecraft Assembly and Test

d. Monitoring of Microbiological Assays

e. Monitoring of Decontamination Procedures

f. Monitoring of Terminal Sterilization

g. Monitoring of Personnel Practices in Biological Control Areas

h. Analysis of Personnel and Hardware Flow for QA Implementation

i. Analysis of Documentation for Data Bank Use

j. Analysis of Monitoring Techniques for Bioburden Prediction Models

k. Review of Procurement Procedures for Microbiological Control and Inspection

l. Contamination Review Board

m. Sterility Control Team

n. Nonconformance Materials Review (including microbiological aspects)

Although this list is not complete, it indicates the range of additional quality assurance activities which can be expected in a planetary program. The additional and perhaps more stringent documentation requirement also needs to be considered.

2.3.2 ORGANIZATIONAL RELATIONS

Quality Assurance will have inter-relations responsibility with several organizations in the performance of planetary and sterilized hardware activity. Among these groups are:

a. Microbiology

b. Facility (clean rooms)

c. Data Systems

d. Engineering

e. Manufacturing

f. Test Operations

Among the interrelated activity will be the evaluation of decontamination and sterilization procedures and reporting and recording microbiological procedure violations by all involved personnel. This includes personnel behavior, dressings, washings, etc., before and during clean room activities.

Quality Assurance will monitor, inspect, and verify all test operations from both a functional as well as a planetary quarantine view point. The same is true for assembly and fabrication activities. For this reason, Quality Assurance will participate in, or concur, in all significant fabrication, assembly, test, microbiological monitoring and related planetary quarantine planning activities. It is a Quality Assurance function to support and cooperate with other functional groups to reduce the probability of any potential quality compromise or contamination of planetary space-systems hardware.

2.4 RECEIVING INSPECTION

This activity is covered in detail in Section 3 of this manual. This detail is possible because there is very little change from the previously used procedures as defined by NPC 200-2 (Reference 2-1) and SR-QUAL-64-13 (Reference 2-2) and these procedures would be adapted.

2.5 FABRICATION AND ASSEMBLY

This activity is covered in Section 4. Although it is recognized that personnel controls have to be exercised in the fabrication and assembly of spacecraft/landers to be sterilized, the degree of control is still in process of evaluation. Clean room controls, as specified, will probably not be required until the subsystem assembly level is reached.

Contamination violations and sterility compromises are to be handled as "Nonconforming Material" and will be adjudicated by the Materials Review Board or the Contamination Review Board.

2.6 TEST AND CHECKOUT

The inspection and test operations will be planned jointly with test operations functional personnel and microbiology personnel to satisfy sterilization and planetary quarantine requirements. All other requirements and plans will be initiated according to procedures and plans formulated for the specific program. The detailed information provided in Sections 4, 5, and 6 of this manual shall be considered for guidance.

Contamination violation and sterility compromises shall be handled in accordance with the procedures outlined in Sections 2.11 and 2.12.

2.7 PACKAGING

Only the problems of microbiologically clean packaging will be considered here, with examples of representative approaches from existing controlled and routine packaging. Packaging problems assume a major importance in a bioclean spacecraft program and are discussed in Section 4.7.

2.8 BIOLOGICAL CONTAMINATION MATHEMATICAL MODEL

The problems posed by Planetary Quarantine Requirements and the subsequent necessity to develop space vehicles which meet predetermined and measurable sterilization requirements can easily be handled by means of mathematical modelling techniques. Sophisticated computer programs have been developed which aid in the ability to monitor, predict, control, and evaluate the bioload conditions throughout the life cycle of a space probe vehicle from assembly through terminal sterilization. This means that the contamination probability can be determined and evaluated in advance of actually undertaking the construction of a space vehicle by providing visibility and traceability of factors contributing to bioload accumulations. Thus, as a Quality Assurance analysis tool, math models are ideally suited for use in space probe sterilization programs. The use of math modelling techniques permits tradeoffs and evaluations to be made of sterilizations requirements upon program costs, system reliability, and manufacturing or testing facility environments (clean room levels), based on manufacturing, assembly and test biological assay data. In addition, a complete data bank is obtained whereby each component's bioload history can be retrieved upon demand.

One other important benefit of using a mathematical model is apparent. Biological assays normally require up to 72 hours to grow cultures, with counts made at 24 hours, 48 hours and 72 hours. Use of math models may permit use of 24-hour counts, thus gaining critical time under certain conditions.

As indicated earlier, the purpose of using math modelling techniques is to provide the capability to monitor, predict, evaluate, and control the bioload conditions through assembly, checkout, test, and perhaps canister mating repair cycles for space vehicles. This capability provides the essential basis for evaluating the total bioload accumulation for both external and internal parts of the space vehicle before thermal sterilization. Furthermore, it permits evaluating quantitatively the probability associated with meeting pre-set sterilization objectives with defined confidence levels. Inputs for the model are obtained primarily from microbiological sources (assays) manufacturing and assembly sources (processing time to perform tasks) and quality assurance sources.

A math model developed by General Electric is operational and is currently being utilized to evaluate bioload conditions on a prototype space vehicle undergoing a series of tests. A similar math model is currently under development by Martin-Marietta (Denver) and used by the Jet Propulsion Laboratory.

The computer program utilized by General Electric is based upon a probabilistic treatment of external and internal bioload quantities and will be described briefly to illustrate such a math model. Poisson statistics are utilized to handle microorganism arrival and departure rates. Expected values and variances of counts due to sequential assembly, test, and other operations are determined. The model predicts the number of organisms on the basis of the prevailing environmental factors of arrival rates, death rates, retention factors, and time required to perform various operations on the vehicle or its components. The model produces a mean value and variance for the bacteria population following each procedure.

Arrival rates are determined on the basis of

a. Retention factors

b. Projected area of the components, subsystems, or vehicle major assemblies

c. Fallout rate

d. Time required to perform tasks

e. Total area

f. Percent of the area contacted during task performance

g. Organism contribution due to contact

h. Environmental controls

Departure rates are determined by:

a. The mean death parameter

b. Time to perform tasks

c. Reduction due to tasks such as chemical and mechanical cleaning, heating, and removal or clipping or material from work in process

Given the biological assay and assembly data, the model yields after each task or process

a. Mean external organism count

b. Internal organism count

c. External variance

d. Mean internal variance

The basic equations utilized by the model are as follows, using the nomenclature shown. Following that, Figure 2-4 shows a computer logic flow chart.

MODEL EQUATIONS

Mean External Count

$$n = \frac{\lambda}{\mu}\left(1 - e^{-\mu\Delta t}\right) + \left(1 - F\right) n_o e^{-\mu\Delta t}$$

Mean Internal Count

$$\phi = \left(\phi_o + F n_o\right) e^{-\mu^*\Delta t}$$

Variance of External Count

$$\sigma^2 = \left[\frac{\lambda}{\mu} + (1 - F)\, n_o e^{-\mu\Delta t}\right]\left[1 - e^{-\mu\Delta t}\right] + (1 - F)\sigma_o^2 e^{-\mu\Delta t}$$

Variance of Internal Count

$$\theta^2 = F n_o e^{-\mu^*\Delta t}\left(1 - e^{-\mu^*\Delta t}\right) + \left(\theta_o^2 + F\sigma_o^2\right) e^{-\mu^*\Delta t}$$

Where

n	=	the mean of the external count
n_o	=	the mean of the initial external count (before the process)
λ	=	the mean arrival rate of bacteria
μ	=	the mean death parameter for external bacteria
Δt	=	the time interval for the process
ϕ	=	the mean of the internal (occluded or mated) count
ϕ_o	=	the mean of the initial internal count
μ^*	=	the mean death parameter for internal bacteria
F	=	the fraction (percentage) of external bacteria that becomes internal during process
σ_o^2	=	the variance of the initial external count (before the process)
σ^2	=	the variance of the external count
θ^2	=	the variance of the internal count
θ_o^2	=	the variance of the initial internal count

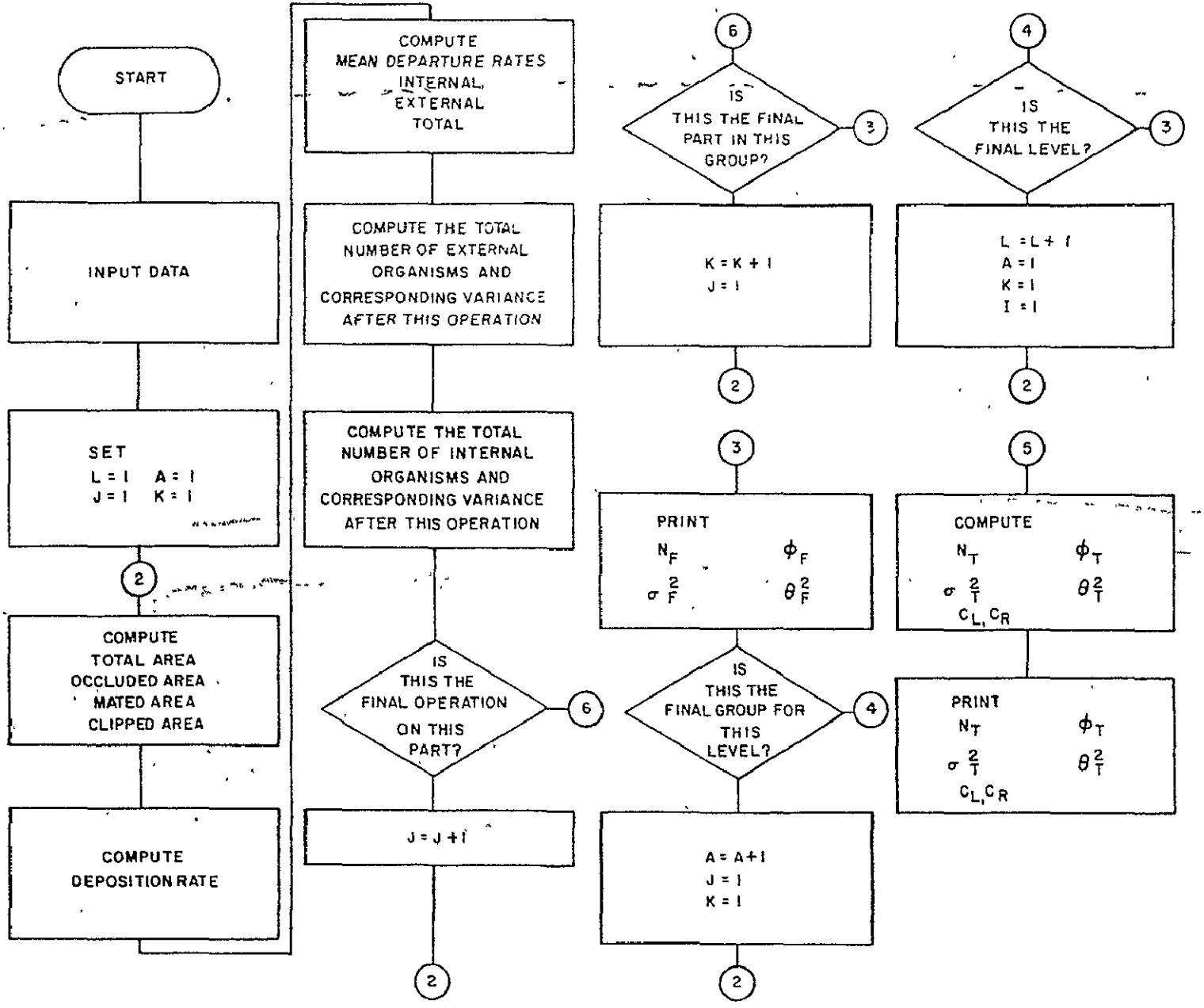


Figure 2-4. Mathematical Model Flow Chart

The organism count is subdivided into three sections:

a. External: The external count gives the mean number of organisms (spores) on any exposed surface of the component.

b. Occluded: The occluded count is the mean number of microorganisms (spores) which lie on the surface of the material, but are totally enclosed by the structure, (i.e., the interior surface of a closed box). The occluded count is entered initially, but is modified as additional areas are enclosed during the assembly of components during manufacturing. The occluded microorganisms (spores) are affected only by natural die-off rate (a function of the environment), and by heat treatment.

c. Mated: The mated count determines the mean number of microorganisms (spores) which are enclosed between two physically mated surfaces. This count is also entered initially and is modified as the manufacturing and checkout process is continued. The mated region microorganisms are affected only by the natural die-off rate and by the effects of heat treatment.

Each component, at any stage in the process, has a part number (Q), a group number (G), and a level number (L). The process is divided into a series of levels, each level consisting of a series of operations on the parts existing at that level, the final operation in a level being the amalgamation of at least two parts to form a new assembly. This assembly becomes a part in the next level.

The parts are arranged in groups according to how they are to be combined at the end of the level. Parts with the same group number G are combined to form one new part for the next level. The parts are numbered sequentially in each group. The effect on the count of combining parts in the final operation of the level is first quoted separately for each part and then as a group total for the parts as formed into the new assembly. Operations are performed on the individual parts according to the operation number (J).

The mating or combining operations generally take a finite length of time, and there is deposition and natural die-off on the surface during this period. The external and internal counts will thus depend on how the external, occluded, and mated areas vary with the time during the assembly. This variation will depend on how mating is done; i.e., whether the area is occluded or mated gradually or near the beginning or end of the process. The method of handling a wide range of different mating processes is to assume that the physical joining occurs at or near the middle of the operation time; the areas in the first half of the process being as they were before the combination and, during the second half, as modified by the combination.

Because of the increased flexibility which becomes available through the use of math models, it is easy to recognize that they offer a wide range of additional capabilities for quality assurance analysis and procedures.

The problems of recontamination analysis and prediction can be handled by the math model. Other applications include:

a. Comprehensive contamination data history listing on all parts of the system

b. Analysis of heat sterilization duration requirements based upon predicted bioload

c. Evaluate effects upon system reliability due to heat soak requirements

d. Identification of areas where sterilization costs can be reduced by predicting where major bioload accumulations are likely to occur and how best to avoid these conditions

e. Tradeoff and optimization of manufacturing, assembly, checkout and test operations in accordance with contamination control objectives

f. Selection of assembly operations and facilities which are most cost-effective

g. Provision overall system management visibility in terms of sterilization effectiveness

But most of all, the use of math modelling in the context of space vehicle sterilization requirements reduces what has previously been a formidable and serious problem of virtually unmanageable proportions.

2.9 TRAINING PROGRAMS

The need for training programs in a planetary spacecraft program which includes planetary quarantine must include not only the normally expected personnel training and certification customary on all scientific spacecraft systems, but also that particularly required by the planetary quarantine requirement.

The former is covered in numerous planetary spacecraft program documents, such as those generated in the several Voyager and Mariner studies, and will not be repeated here.

The latter is unique to a planetary landing vehicle and has been described in Section 1.4 of this document. It is presented there because of the unique microbiological requirements.

2.10 DATA SYSTEM

The microbiological contamination data bank is discussed in Section 1.5 because it is a unique planetary quarantine requirement. This section covers the highlights of the remaining data system requirements for a planetary program.

2.10.1 GENERAL

The data reporting system provides quality and discrepancy information from the parts level through field operations. The following documentation is customarily used to accumulate and report quality data and information:

a. Inspection Record Forms

b. Nonconformance Report Form

c. Inspection Report Form

d. Performance Data Cards (Parts)

e. Performance Data Sheets (Articles)

f. Failure Report Form

g. Data Control Sheet/ Nonconformance Report

h. Supplier Performance Data Sheets

i. Supplier Failure Reports

j. Materials Lab Analysis Reports

Item a is used by all in-house inspection operations. Items b, c and d are used primarily at Receiving, Receiving Inspection, Parts Laboratory Inspection/ Test, Subassembly Fabrication and Inspection levels. Items e and f apply for component, subsystem and system test levels while item g is used in field operations. Items h and i are required from subcontractors and suppliers and established by contractual commitment as part of the overall control of purchased articles. Item j is used to report physical and chemical analysis results on samples of material, finishes, coatings, etc., required for acceptance of such items by Receiving or In-Process Inspection.

To aid in disseminating concise failure information to all operations, a Failure Summary Log is compiled and maintained current. This log groups all failure data for each specific article together in summarized form arranged chronologically and provides a useful, quick reference tool for checking failure histories and corrective actions taken. The log also references, by number, formal failure analyses performed which provide additional detail on specific failures.

Corrective action is determined by review and analysis of reported failure information and also the results of special investigations, evaluation testing, etc., as required to substantiate such action. Formal failure analysis is required for all performance discrepancies reported on components, subsystems and systems. All resources of the Project Group are used as needed to determine and accomplish required action. Corrective actions taken are documented

on formal failure analyses or by notation on discrepancy and failure report documents when action is obvious or formal analysis is unnecessary. Quality aspects of article specifications and drawings are periodically reviewed on the basis of all pertinent data reported to identify changes necessary to assure a quality level consistent with program requirements. All failure data and information is transmitted to the Reliability Operation to facilitate evaluation for trends, Mean Time Between Failures (MTBF) goals, performance variability, compilation of the Failure Summary Log, etc.

2.10.2 DATA REPORTING DOCUMENTATION

The Inspection Record, Nonconformance Report, and Inspection Report provide direct indication of design and fabrication deficiencies. Review and analysis of this information by Quality Assurance determines adequacy of process control, quality trend and indication of where and when specific quality training and certification or recertification of personnel is needed. The analysis results determine required corrective actions and are preliminary indications of quality levels.

The Performance Data Cards, Performance Data Sheets, and Failure Reports provide performance history and records for all articles including type approval test results. Review and analysis of this information and Inspection Reports Identifies possible design improvements and indicates which articles have limited or critical life characteristics. Information on Unified Failure Reports and Inspection Reports is also analyzed to identify problem areas and determine the need for special investigations or analyses necessary for solution. The Data Control Sheet/Nonconformance Report provides interface with field experience and supplies feedback information for analysis and initiation of corrective actions required inhouse.

Subcontractor/Supplier/Vendor Failure Reports, Analyses, and Performance Data provide indication of quality levels on purchased articles. Suitable inputs for establishing Subcontractor/Supplier/Vendor quality ratings are also derived from this information. When these inputs show deterioration from the acceptable performance level, detailed review is performed to determine the cause and the results submitted to The Subcontractor/Supplier/Vendor for corrective action.

2.10.3 ORGANIZATION

Quality and discrepancy data is generated by Subcontractors/Suppliers/Vendors as well as the following organization elements:

a. Receiving Inspection

b. Parts Laboratory (parts screening, special tests, etc.)

c. Process Control Inspection

d. Component Test

e. System Accumulation Inspection

f. System Test

g. Biological Contamination Control

h. Field Inspection and Test

2.10.4 ACCUMULATION AND RETRIEVAL

To handle efficiently the volume of quality data necessary for a Project and provide for rapid data retrieval, a Configuration Information System (CIS) will be established. This operation will receive input data and information by means of the reporting documents referenced in Section 2.10 and transfer it to punched card form. These data cards will be accumulated and retained by the CIS for use in providing rapid processing and retrieval services for all other operations. Article performance profiles can be obtained through this retrieval capability. One valuable feature will be the inclusion of a discrepancy/failure cause code number on all discrepancy or failure data cards. This code will provide means fo retrieval by various breakdowns such as location, type, test level, supplier, manufacturing error, etc.. The services of this operation will:

a. Support preparation of quality status reports

b. Provide data for historical reviews

c. Aid in evaluating the effectiveness of corrective actions, and

d. Assist in preparation of failure analyses. Examples of data reporting flow diagrams are shown in Figures 2-5 and 2-6.

2.10.5 DESIGN AND DEVELOPMENT

To provide records necessary for traceability in solution of problems, performance characteristics history and trade-off decisions, all quality data associated with design and development will be recorded in engineering logbooks. These data will include details of experimental tests investigations, failure analyses, descriptions of tests, numerical results and conclusions. The development data will not be entered in the CIS, but will be retained by Design Engineering for reference as required.

2.10.6 QUALITY STATUS REPORTS

The CIS will supply the majority of information required for preparation of periodic quality status reports by Quality Control. These reports will include current profiles of article performance, quality goals achieved, results of analyses and corrective action taken. Interpretation, recommendations, conclusions and projected action based on this information will augment the basic data reported. Copies of the report will be supplied to Program Management and NASA.

2.10.7 END ITEM REPORTS

The CIS will also provide inputs for the quality data required in end item reports. Narrative interpretation and conclusions will accompany these data. Use of the configuration information system will enhance the timeliness and accuracy of the information submitted in both the quality status and end item reports. In addition to the documents referenced in Section 2.10.1, the following data and information documents are generated for configuration control and log history:

a. Break of Inspection Card - Records changes made in articles at in-process level

b. List of Material (L/M) - Defines system final configuration.

c. Break of Inspection Record (BOI) - Identifies system changes in configuration chronologically and shows serial and part numbers of articles removed and replacements installed

d. Failure Analyses (System) - Identifies troubles and malfunctions encountered and the corrective action taken

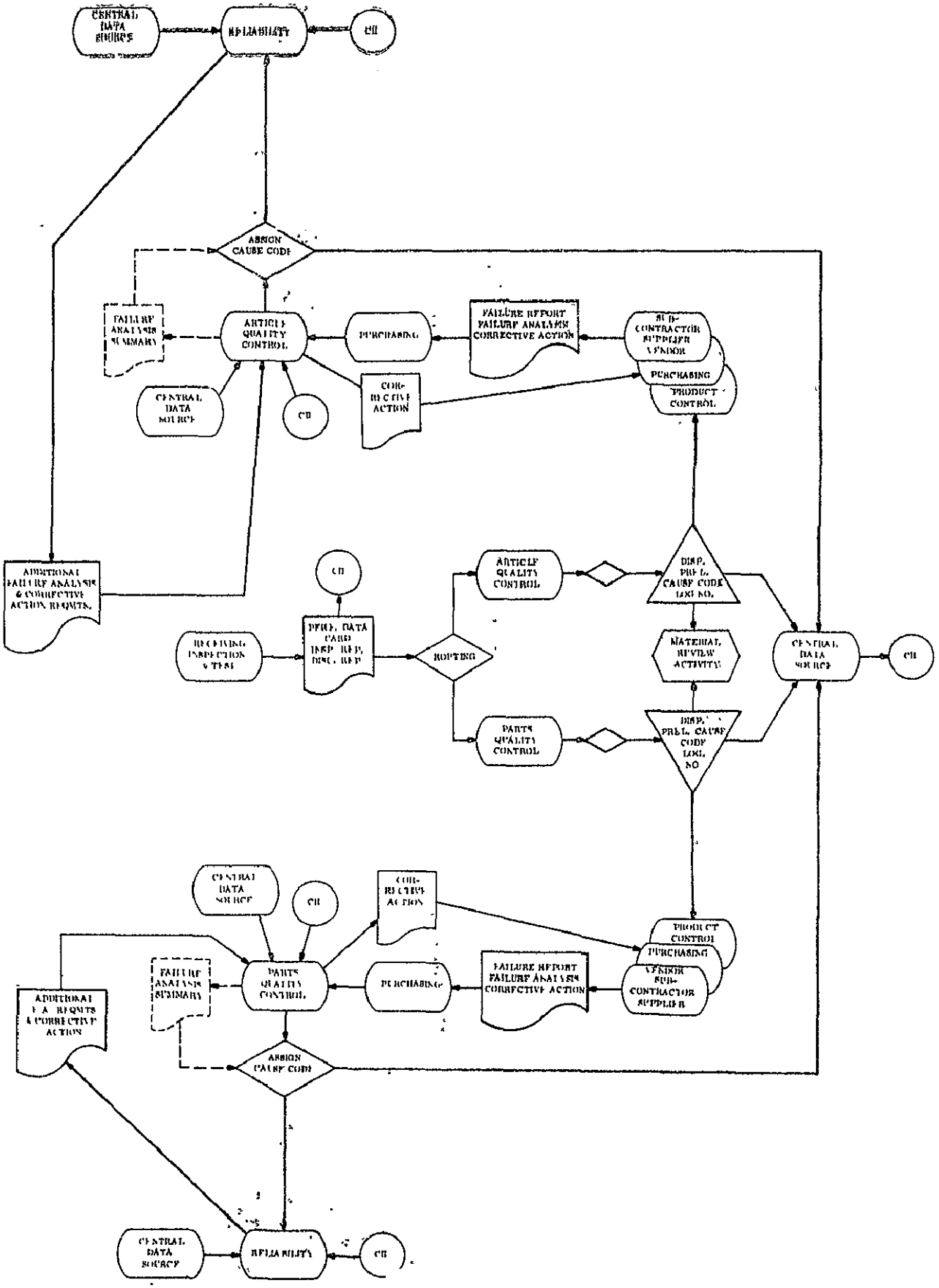


Figure 2-5. Receiving Inspection and Test Data Flow

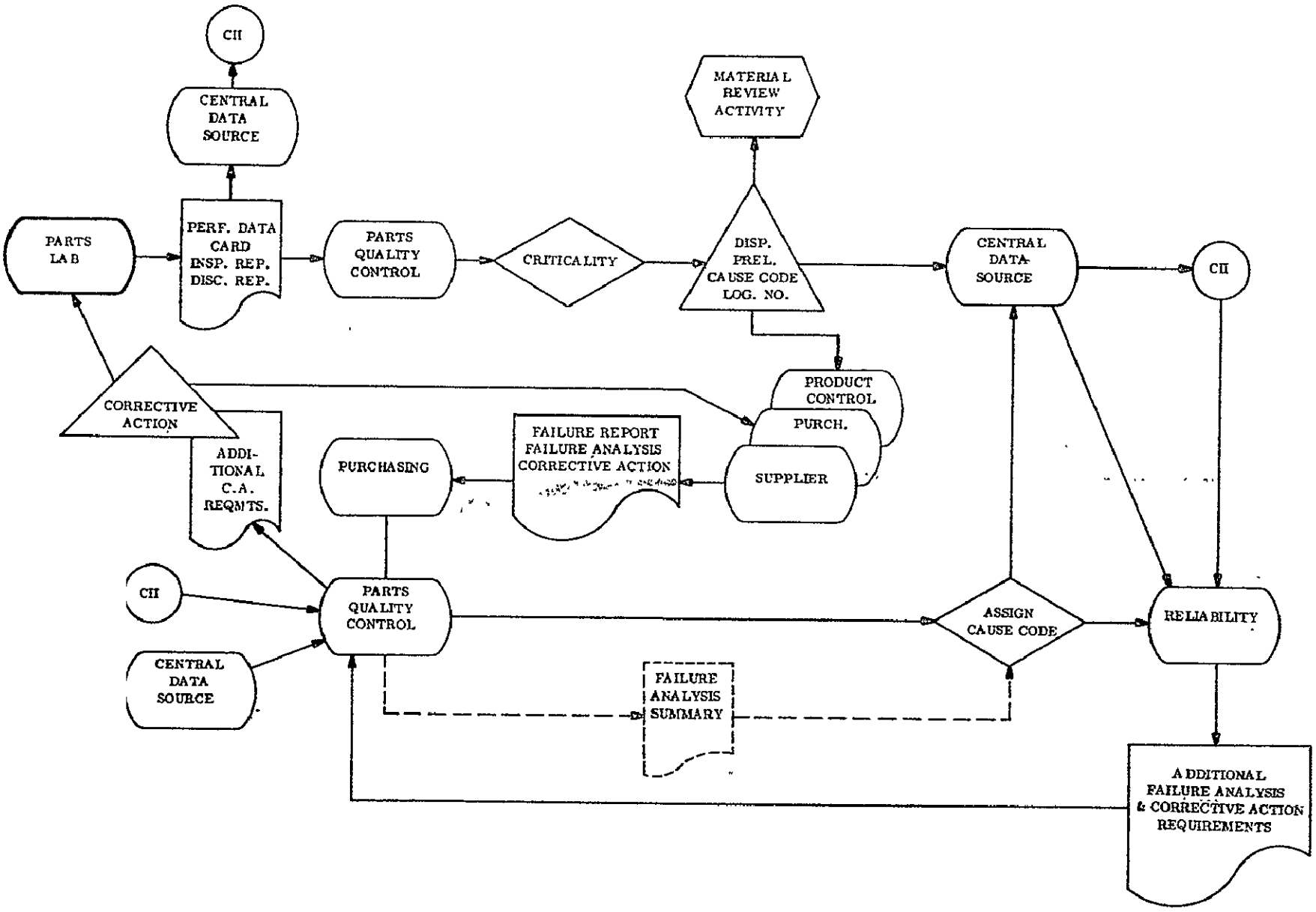


Figure 2-6. Parts Laboratory Flow

Retest and incomplete test status is obtained by review of system test data records. These documents provide additional information required for preparation of the end item report.

2.10.8 RECORDS

Inspection results are recorded in numerical form where possible and practical on Inspection Record Forms. These are filed by each Inspection Operation to provide traceability and reference information, if needed for subsequent failure analysis. Evidence of completed inspection is accomplished by stamping both the Record Forms and the article. Discrepancies are documented by use of the Nonconformance Report, Inspection Report, Unified Failure Report, or Data Control Sheet, depending on the inspection level. Functional performance characteristics data for complete articles are recorded on TP Performance Data Sheets which also provide for recording operating time and identify each characteristic as critical, major or minor. All performance data for critical and major characteristics is recorded as actual variable measurements where it is possible and practical. Minor characteristic data are recorded by either attribute or actual variable measurement. Copies of these data sheets are maintained on file. The original will be transmitted to the CIS. Discrepancies and failures are documented on the Unified Failure Report, Data Control Sheet and/or Inspection Report Forms. In addition to these detailed records the majority of this information will be maintained in punched card form by the CIS.

2.11 AUDITS AND CORRECTIVE ACTION

The system of discrepancy and failure reporting through the use of the Nonconformance Report Contamination Violation Report, Inspection Report, Unified Failure Report and Data Control Sheet/Nonconformance Report provides means for identifying immediate corrective action directly on the document. Failure analysis is performed when the cause or corrective action is not obvious and includes a cross-reference to the failure reporting document. Corrective actions are directed toward elimination of the initial cause factor(s) to the maximum extent possible, consistent with schedule, cost, ease of implementation and degree of cause isolation achieved. Periodic audit and followup is performed to verify that corrective actions have been implemented and are maintained.

2.11.1 TRENDS

All data generated at any point requires review and approval before resumption of the material flow. This review includes notation of any major changes in characteristics and permits early recognition and initiation of corrective action. When the quantity of articles is large enough to provide sufficient data for meaningful control charts, these are prepared and maintained by Process Control for parts and subassemblies. Periodic reviews by Reliability of accumulated data are performed to identify less obvious trends for components, subsystems and systems. This trend information is transmitted to Quality Assurance for use in determining necessary corrective action. Problems or potential problems revealed by review of performance and failure data which require action in areas other than the one where the discrepancy or variation is detected, are interfaced with other operations to provide a coordinated action effort.

2.11.2 FAILURE ANALYSIS

Failure analysis are performed to determine the specific causes of the failure or discrepancy and the required corrective action. Where applicable, special investigations, tests, teardown evaluation, etc., are conducted to support the analysis. The services of Design Engineering, Materials and Processes, Parts Laboratory and Subcontractors/Suppliers are used to ascertain the best and most economical solution. The failure analysis report includes complete identification of the discrepant material and the applicable failure reporting document. Also included is a brief description of the failure, summary of all analysis performed, material disposition, and the corrective action taken or planned. When analysis shows that a potential problem may be present in existing parts stock or in completed articles, corrective action includes a "hold" on the suspect parts stock and recall of completed articles. Suitable investigation, inspection and test are then employed to determine disposition of the suspect material. When corrective action requires rework of articles which have previously completed fabrication and test all affected operations are notified of the requirements in writing.

When required action has an impact on delivery schedules or field use, Project Management is also notified so that a satisfactory plan for accomplishment of the action can be formulated consistent with project requirements.

2.11.3 FAILURE ANALYSIS/REVIEW

A Failure Analysis Review Board (FARB) will be established in the Project Office to review and evaluate all failure analyses and corrective actions. The purpose of this review and evaluation is to assure adequacy of analysis and identify any deficiencies or incomplete actions. When a formal analysis is required, the Board assigns and issues an identifying log number. The assigned log number is referenced on all documents issued pertaining to the failure, thereby providing means for correlating these documents for subsequent use. Periodic status reports of analyses are issued which provide a listing of all current analyses in progress and those which have been completed and reviewed, but held open for corrective or additional action. The review board will normally consist of one representative from each of the following operations:

a. Quality Assurance (Chairman)

b. Reliability

c. Design Engineering

d. Manufacturing

e. Standards

f. Materials and Processes

g. Planetary Quarantine

The board meets periodically to review new and supplemental analyses issued and the status of action items generated at previous meetings. FARB representatives receive copies of all analyses issued for individual review before board meetings. This provides time for detailed review by the representatives so that review, conclusions, recommendations and action items at board meetings can be efficiently completed.

When the throughness of the analysis and corrective actions are adjudged adequate and complete, the board accepts the analysis report and designates it as "closed." Satisfactory evidence that corrective actions identified in the report have been implemented or initiated

is required by the board to close the report. Examples of such evidence are documents of changes in design, process, procedure or test equipment; written notifications to personnel and Subcontractors/Vendors/Suppliers; and initiation of orientation/training actions. When analyses or corrective actions are found deficient or incomplete, the report is held "open," pending receipt of supplemental information correcting, clarifying or completing the "open" items. Board representatives are assigned action items to expedite and assure adequate followup of "open" items requiring action in their respective operations. A summary report of the minutes and results of board meetings is issued for information purposes to all affected operations and personnel. The board also compiles and maintains current the Failure Summar Log. This log includes brief information on results of formal analysis, informal analysis and corrective actions for all discrepancies. Figure 2-7 shows the interrelationships involved in the operation of the Failure Analysis Review Board.

2.11.4 SUBCONTRACTORS/SUPPLIERS

Failure data reporting is established as a contractual requirement for all articles purchased from subcontractors and suppliers. Immediate notification of failures is required to permit earliest possible assessment of any impact on articles previously received. It is also required that the immediate notification be confirmed by detailed written report. In addition to the detailed reports of failures, detailed failure analyses including information on the corrective action taken or proposed are required. Minimum requirements, specifying the type of data and information to be submitted, are defined in the procurement documents, and also include maximum time limits for submission of this information. The data and information received are reviewed and evaluated for completeness of analysis and adequacy of corrective actions. The subcontractor or supplier is notified of any deficiencies and required to submit supplement reports clarifying or correcting the deficiencies noted. For failures which occur on purchased articles previously received, a Unified Failure Report and Inspection Report are prepared and the article returned to the vendor for analysis and corrective action. When necessary, the subcontractor or supplier is requested to initiate specific corrective action measures which have been identified by review and evaluation of performance and failure data accumulated after receipt of the purchased article.

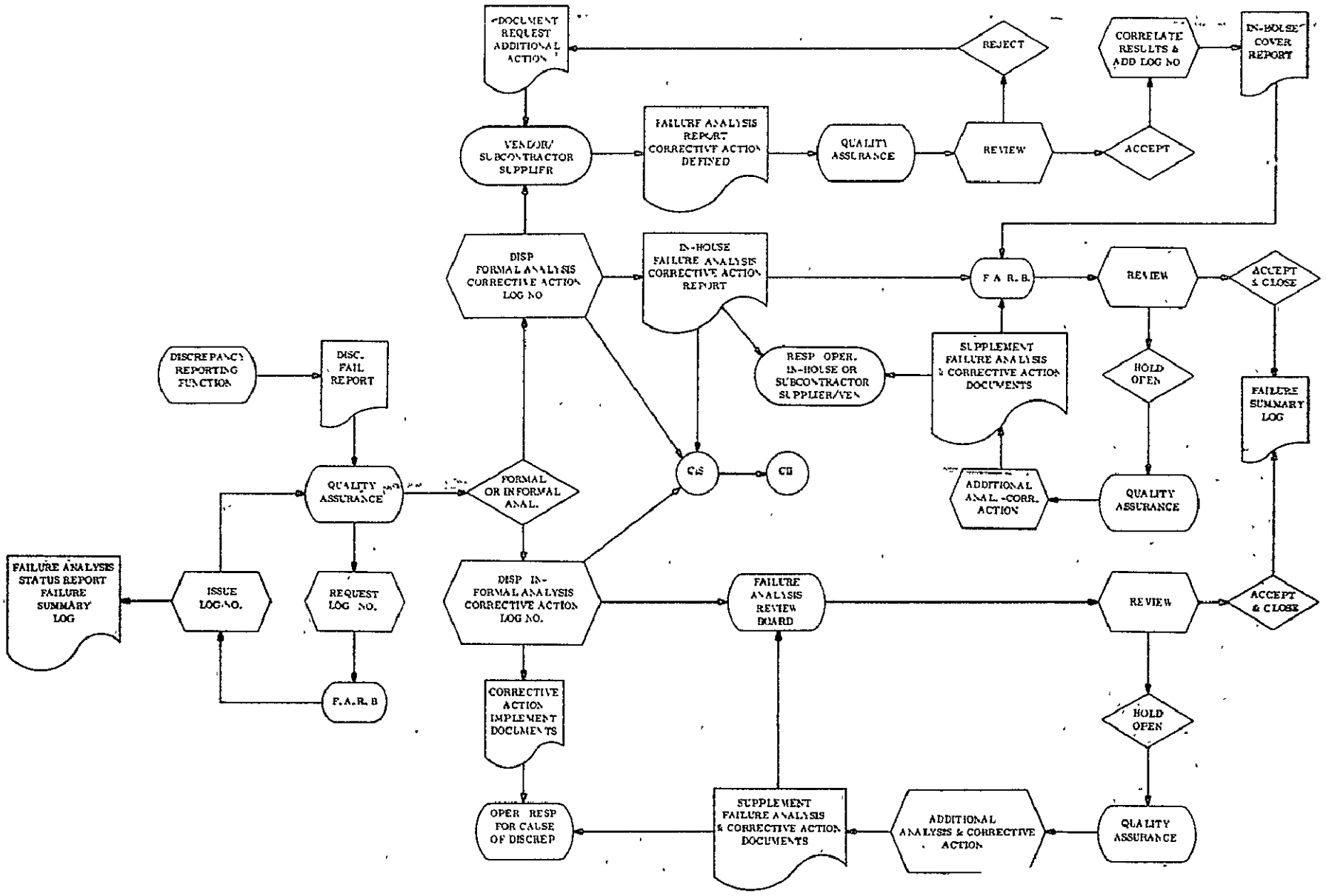


Figure 2-7. Failure Analysis Review Board Operation

2.12 QUALITY ASSURANCE AUDITS

2.12.1 GENERAL

The audit function is geared to advise management with current factual data regarding program compliance and the effectiveness of quality management systems on product quality. The audit group will be comprised of personnel who have general knowledge in program requirements, management systems, contractor/subcontractor/vendor auditing, manufacturing processes and controls, product verification, planetary quarantine, field operations, and quality control/ reliability specifications.

2.12.2 AUDIT PLAN

The auditing program will be designed toward and implemented to provide positive assurance that: (See Figure 2-8)

a. Contracted requirements are being complied with.

b. The established Quality/Reliability system is complied with and changed if needed to satisfy Program requirements.

c. Processes (soldering, welding, potting) are rigidly controlled to prevent defects.

d. Completed articles are manufactured and/or tested to the specified engineering definitions.

e. The Contractor, Supplier, and Subcontractor shall be monitored for compliance to contract requirements.

f. Field Operations are compliant with the accepted Field Program Plan.

g. Planetary Quarantine is not compromised.

The auditing program shall, for example, be focused to the prevention of:

a. Any misunderstanding of Program requirements that could prove costly to the program and impair schedule commitments, e.g., magnetic requirements, type approval and proof test model requirements, supplier/subcontractor control requirements, material review requirements

b. Implementing existing quality/reliability procedures which are in any way contrary to contract requirements including NASA Specifications NPC 200-2 and NPC 200-3

c. The degradation of in-process articles that may be caused by manufacturing processes (paint, soldering, bonding, wiring, etc.) and methods

d. Installing into the end items any articles which do not agree with the specified engineering definition or planetary quarantine

e. Correlation omissions by NASA, Supplier, Subcontractor regarding type approval and proof test model testing

f. Conducting confidence test before the review of the end item logbook and its verification to the latest planetary quarantine or engineering definition.

2.12.3 ACCOMPLISHMENT OF AUDIT PLAN

To accomplish the outlined tasks and their associated examples, schedules shall be established and submitted to Quality Assurance management on a continuing basis for review and approval. Checksheets for each major task will be developed in sufficient detail to provide a qualitative measurement for management action. The Management Report will accentuate critical areas that require action. Corrective Action Request will be forwarded to the manager responsible for nonconformance that occurs within the particular work scope. This formalized system will state the nonconformance, provide recommendations for correction and specify that corrective measures must be in place within a specified time period. Quality Assurance will participate as a member of a Management Audit and Review Team which will appraise Supplier's, Vendor's, and Subcontractor's progress.

2.12.4 CONTAMINATION VIOLATION AND CONTAMINATED REVIEW BOARD

The specific need for a contamination violation audit and reporting procedure is based upon the requirements of planetary quarantine. This procedure, in conjunction with the mathematica contamination accumulation model information, is necessary to assure control of the microbiological cleanliness of the planetary lander. The functional group to which such reports and audits are addressed is the Contamination Review Board (CRB). The function of this Board is somewhat similar to that of a Nonconforming Materials Review Board (NCMRB), except that it is made up of personnel from Quality Assurance, Microbiology, Facilities, Engineering, and other cognizant groups.

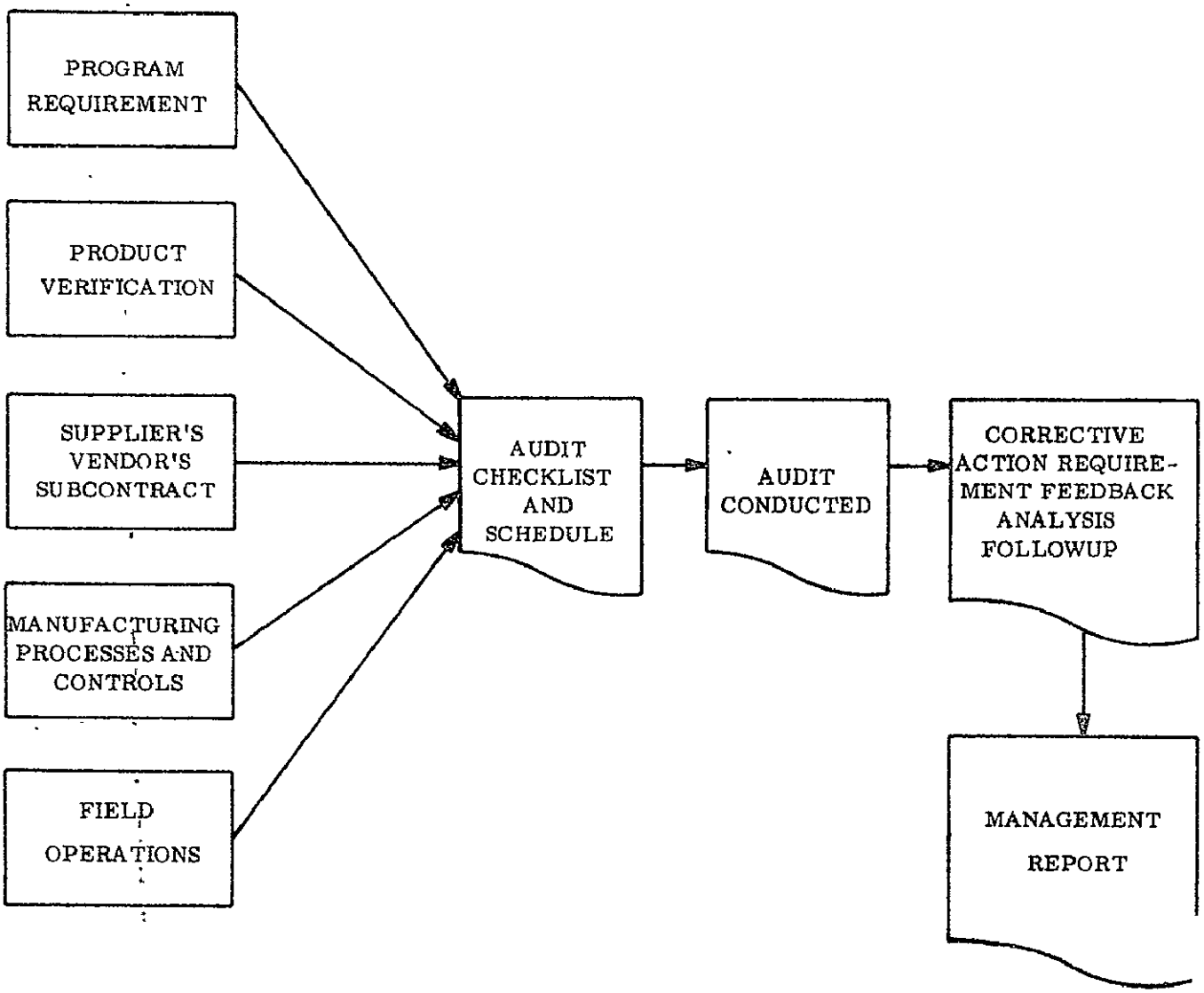


Figure 2-8. Information Flow Plan of Quality Auditing Program

Contamination violations can be and must be reported by anyone observing such occurrences. Although visual monitoring will be required during all spacecraft assembly and checkout operations, both with and without aid of a closed circuit TV system (Ref. 2-8), this does not diminish the responsibility of all personnel engaged in the planetary lander program to report violations of both spacecraft procedures as well as facility procedures. These violations shall be channeled through the Quality Assurance representative, who will initiate the necessary action with the concurrence of microbiologists, planetary quarantine and facility personnel. The Contamination Review Board (CRB) represents the final disposition authority for contamination violations and will be convened if disposition of violations cannot be effected at other levels.

Reference 2-9 describes the functions of a Contamination Review Board as follows:

a. Review the reported discrepancy and determine whether a contamination problem exists.

b. Determine the disposition or action to be taken regarding the contaminated facility, hardware, or personnel.

c. Assure that effective followup ensures that corrective action is taken to remedy the cause of the contamination.

Further details of the CRB authority and procedures must be established by the cognizant project office and the NASA Planetary Quarantine Officer.

2.12.5 MATERIAL REVIEW BOARD

A Material Review Board (MRB) will be established for determining the disposition of nonconforming materials. Guidelines of the MRB function are as follows:

> When material is first found to depart from specified requirements, it will be properly identified as nonconforming and isolated from normal channels of fabrication and processing. Material submitted for material review action will be routed to holding areas mutually acceptable to the Project Group and the Government representative. Where removal from normal channels of fabrication is impractical due to the size or configuration, marking or tagging will be accomplished in a manner to assure positive identification as nonconforming.

All nonconforming material will be reviewed by Materials Review Board personnel. If the material is obviously unfit for use or is found to be uneconomically repairable, it may be scrapped in accordance with the project's Government-approved procedure for identifying and disposing of scrap. The project may authorize the return of nonconforming material for completion of operations, rework to original specifications, or repair to NASA-approved repair procedures.

Minor nonconforming material will be submitted to the Material Review Board for disposition and will be disposed of in accordance with the decision of the board. Minor nonconformances will be summarized on the applicable quality form for delivery with the end item.

Major nonconforming material will be authorized for use only if a waiver is granted by the contracting officer. The Material Review Board will conduct an investigation and submit recommendations for dispositions to the Contracting Officer.

2.12.6 DEFINITIONS

Applicable definitions areas follows:

a. Nonconformance - Any departure of a product from specified requirements.

b. Minor nonconformance - Any nonconformance other than major that does not materially reduce the usability of the produce for its intended purpose, or is a departure from established standards having no significant bearing on the effective use or operation of the product or associated items.

c. Major nonconformance - Any nonconformance that could result in hazardous or unsafe conditions for individuals using or maintaining the affected product or could adversely affect reliability, durability, performance, interchangeability, weight, or the basic design intent.

d. Material Review Board - A formal Project-Government board established to determine the disposition of minor nonconforming material and to recommend the disposition of major nonconforming material. The Material Review Board is made up of a representative of the Project Group whose primary responsibility is product quality, a representative of the Project whose primary responsibility is design, and a Government representative assigned.

The project group will provide for the selection, evaluation, approval, maintenance, and control of all inspection standards, gages, and measuring and test equipment necessary to determine conformance with specification, drawing, and contract requirements. All measuring equipment will be calibrated at scheduled intervals, when required, against certified standards which have valid, known relationships to the National Bureau of Standards. Records will be maintained indicating the date of the last calibration and the next due calibration date. The due date and other identification attesting the due date of the next calibration will be displayed on each independent item of equipment. The contractor shall provide the procedures and means for periodic operational checks to be performed prior to use of specified measuring equipment.

2.13 GENERAL GUIDELINES

The guidelines described in this section form the MSFC analysis and checkout philosophy (Reference 2-2). These concepts have been implemented on many missile and space programs and differ here only in emphasis and application. They also must be supplemented by planetary quarantine requirement guidelines.

The flow of events shall follow a logical, well-planned sequence that permits adequate analysis of each component and/or system with a minimum of nonessential duplication, and with the most efficient use of manpower, equipment, and facilities.

The building-block principle of testing shall be utilized. This means that components are tested individually before they are required to perform in subsystems, and subsystems are tested individually before they are required to perform in systems.

Operations shall be integrated to utilize the available time most efficiently and facilities most effectively. All operations will be accomplished in a logical sequence and the results recorded in a format meaningful for future use. Testing shall be planned to accommodate fault isolation routines without interrupting all other operations.

Analysis and checkout operations should be developed from concepts based on the most versatile selection of manual and automatic systems to arrive at the optimum balance between man and machine. The end result of automation should be equal to or better than the end result of alternate methods.

Organizations responsible for analysis and checkout shall use trained, skilled personnel who throughly understand the specimen and shall perform independently of the design and manufacturing elements. They shall establish criteria derived from design specifications and design objectives and shall be responsible for accepting or rejecting the results.

No analytical or checkout operations shall be performed, except by use of procedures which have been submitted to the procuring activity in accordance with contractual documents.

An organized data processing plan shall be developed and implemented. This plan shall assure that all required data are processed and delivered to cognizant organizations.

Test operations shall incorporate fail-safe provisions which assure return to a safe condition in the event of a power failure or other emergency.

Replacement of rework of parts shall require that appropriate analyses and tests be rerun to verify that the new or reworked part is compatible with and meets the specified requirements.

Standardization of equipment, procedures, and techniques shall be accomplished where it is practical and where it does not compromise objectives.

Inspection stamps that are traceable to the individual responsible for the analysis will be used to indicate concurrence. The use of these inspection stamps shall be in accordance with contractual documentation.

Parts, components, or assemblies intended for flight or for assembly in an operational support system will not be used as test fixtures for testing of other such components. No part, component, or assembly that undergoes qualification testing will be used in a flight or operational support system.

The detailed test plans for the various checkout operations will assure the efficient application of resources. Test equipment used at the factory test sites shall have accuracy and ranges comparable to that used at all other test sites in order to ensure consistency of test results.

Consideration shall be given to the reasons for analysis or checkout. The mere ability of an item to perform a function is not the criterion for acceptance. Ability to perform its function when required and in the proper mode is the important item. Thus, engineering evaluations of the test results are required.

The contractor shall implement a system to feed back rapidly to suppliers the information necessary for correction of deficiencies detected during any phase of activity.

2.11 REFERENCES

2-1. "Quality Program Provisions for Space System Contractors," NASA Quality Publication NPC 200-2, April 1962.

2-2. "Space Vehicle Stage Analysis and Checkout Guidelines," NASA George C. Marshall Space Flight Center Publication SR-QUAL-64-13, May 1964.

2-3. "Quality Assurance Provisions for Inspection Agencies," NASA Quality Publication NPC 200-1, April 1962.

2-4. "Development of Manufacturing Procedures for Planetary Spacecraft to be Sterilized by Heating," General Electric Co. Report 66SD4398, Contract NAS8-11372, July 1966.

2-5. Kapell, G. F., McDade, J. J., and Gavin, T. R., "Experimental Assembly and Sterilization Laboratory (EASL) Operations: Phase I", Technical Report No. 3L-941, Jet Propulsion Laboratory, Pasadena, California, April 1966.

2-6. "Sterilization Assembly Development Laboratory Quality Assurance Program Plan," (AVCO Corp. Contract JPL 951624) JPL Document SADL 002.01, Jet Propulsion Laboratory, Pasadena, California Aug. 1967.

2-7. General Electric Co., "Development of Quality Assurance Procedures for Planetary Spacecraft to be Sterilized by Heating," Final Report, Contract NAS-8-21139, G. E. Doc. 68SD4250, December 1968.

2-8. Gavin, T. R., "Visual Monitoring During Assembly of Sterilizable Planetary Landing Capsule," Tech. Memo 33-345, Jet Propulsion Laboratory, Pasadena, California, 1967.

2-9. AVCO Corp. "Sterilization Assembly Development Laboratory - Quality Assurance Program Plan," Report for Jet Propulsion Laboratory, JPL Doc. - SADL 002.01, August 1967.

2-10. General Electric Co., "Sterilization Math Modeling Techniques," Presentation at NASA Planetary Quarantine Advisory Committee, Cape Kennedy, Florida, April 1-3, 1968.

SECTION 3
RECEIVING INSPECTION

SECTION 3
RECEIVING INSPECTION

3.1 INTRODUCTION

This section provides the basic guidelines for the receiving inspection activity and is based extensively on material from Reference 3-1. Receiving Inspection shall provide assurance that all incoming materials conform to the quality (including microbiological) specifications and requirements stated in the purchase order. Any special requirements shall be detailed by the cognizant engineering and microbiological personnel at the time of purchase.

In general, the purchased hardware will be supplied to withstand the terminal heat sterilization cycle, but will not be sterile upon receipt. This hardware will be subjected to the normal aerospace receiving inspection and/or tests. All hardware and supplies received including microbiological assay materials, raw materials, parts, components, assemblies, etc., will be subjected to inspections and/or tests to assure conformance to the applicable specifications, standards, and drawings. These inspections and tests will range from visual, dimensional,and functional analyses at the suppliers plant to detailed analyses of chemical and physical properties requiring special laboratory facilities. Any sterile or decontaminated materials or supplies received will require special handling,and the inspection personnel should have additional training in these areas.

All receiving inspection documentation, such as test and inspection data, vendor data, failure reports, nonconformance reports, sterility certifications, and corrective actions shall be maintained and will become a part of the historical file on the applicable item. These records shall be maintained for a time period specified by the particular contract.

3.2 GENERAL OBJECTIVES

The overall objectives of the receiving inspection activity are to ensure quality conformance of all purchased items and Government-furnished equipment received. By verifying the quality and the count of all incoming items and material, it can be ascertained that the supplier's material complies with the quality standards and requirements as stated in the

procuring document. By eliminating nonconforming materials from entering the stock areas, failure costs in subsequent assembly operations can be reduced.

The receiving inspection acitivity shall provide a well-planned and documented quality inspection, test, and analysis that will determine the condition and count of all components, parts, etc., on their arrival at the contractor's facility. Receiving Inspection will normally perform visual and dimensional checks and verification of all drawing and specification requirements. The extent of the inspection will depend on the contractual requirements.

Normally, receiving inspection will not perform chemical and physical analyses of raw materials, radiographic inspections, sterility or contamination analysis, leak tests, or mechanical and electrical functional tests. These types of analyses require special skills and facilities and are conducted by other organizations for the receiving inspection operation. The results of these analyses are returned to receiving inspection and become a part of the historical file.

3.3 GENERAL REQUIREMENTS

To assure that the objectives of the receiving inspection function are met, the receiving inspection operation will meet, as a minimum, the requirements based on SR-QUAL-64-13 (Reference 3-1) or similar documents as excerpted here, with additions specifically intended for a planetary spacecraft.

a. Inspect and/or test all components, parts, and subassemblies in accordance with the specifications and/or requirements specified in the contract and in accordance with the purchase order.

b. Utilize approved inspection and/or test procedures, techniques, and equipment for measuring dimensions, voltages, frequencies, pressures, temperatures, and hardness. Employ proper test stimuli, excitation and/or other special requirements.

c. Schedule mechanical and electrical functional testing into the appropriate functional test support area.

d. Determine the visual rejections, dimensional rejections, electrical malfunctions, and all out-of-limits performance.

e. Take timely corrective action.

f. Document all receiving inspection results.

g. Determine and evaluate all procedures, data, and statistics to assure that the inspection and/or test preparation requirements and objectives have been accomplished before stocking materials.

h. Assure that suppliers qualify and requalify parts as required by the contract. Records will be kept for failure ratio inspection, and a specified number of parts will be run at a maximum rate condition for a specified time period.

i. Collect the inspection and/or test data and process it for evaluation of results with the test data furnished by the suppliers. This data will be used as an input for an effective supplier rating system and to assist in defect trend information.

Planning and performing inspections and tests on all procured articles will verify that the quality requirements of the purchase order have been satisfied either at the source, at the contractor's plant, or both.

a. Inspections performed at the receiving activity will, as a minimum, include verification of all drawing and specification characteristics that have not been source-inspected by the contractor and which can be verified without disassembly of the article. Particular emphasis will be placed on those characteristics for which deficiencies may not be detected during subsequent inspections and tests. The quantity and degree of inspection performed will be consistent with the critical nature of the article, the information available from previous inspections and tests, and the quality history of the article. Statistical sampling techniques may be used, where applicable, subject to NASA approval.

b. Inspection and test equipment, drawings, specifications, and instructions shall be available in the receiving inspection area for reference in performing the necessary tests and inspections. Where the cost of certain inspection or test equipment prohibits duplication of the supplier's inspection equipment in the receiving inspection area or where the inspection may compromise the sterility, as in the case of sterile petri dishes, culture media, etc., the inspection or test operations shall be performed at the supplier's facility.

c. Procured articles subject to age deterioration or other degradation will be accompanied by an indication of the data at which the useful life will be expended. All such articles will be adequately protected in subsequent storing and handling operations. A system for removal should be established for items that have exceeded their shelf life.

d. Chemical and physical tests necessary to verify material quality will be conducted on test specimens submitted with purchased articles.

e. Chemical analyses, microbiological assays, and physical tests necessary to verify that raw materials conform to specifications will be periodically conducted on samples randomly selected from the raw materials received.

Physical separation of raw materials and purchased fabricated articles for sterilizable systems will be maintained. This will provide, as a minimum, separation of:

a. Materials or articles awaiting inspection and test results

b. Conforming materials or articles

c. Rejected materials or articles

3.4 PLANNING AND SCHEDULING

A receiving inspection activity requires detailed planning and scheduling in order to accomplish complete and accurate tests and inspections to meet over-all end-item delivery dates. Components and materials quality control flow charts that designate where inspection and test stations are required and what is to be accomplished at each station will be prepared. Using the flow charts, the time at each station can be stipulated and the time for the entire cycle estimated. This time-sequenced flow chart enables detections of critical areas so that proper emphasis can be applied to meet major milestones, program schedules, and ensure that end-item delivery dates are met.

The flow chart (Figure 3-1) shown on the next page illustrates equipment hardware flow, through a receiving inspection facility. In order to determine end-item delivery dates, realistic scheduling should be based on the time cycle for each of the areas shown. Figure 3-1 depicts the receiving inspection functions and shows the support functions for special tests.

Using the chart shown in Figure 3-1, time required at each area can be accurately computed in the receiving inspection activity and an over-all test and inspection time cycle can

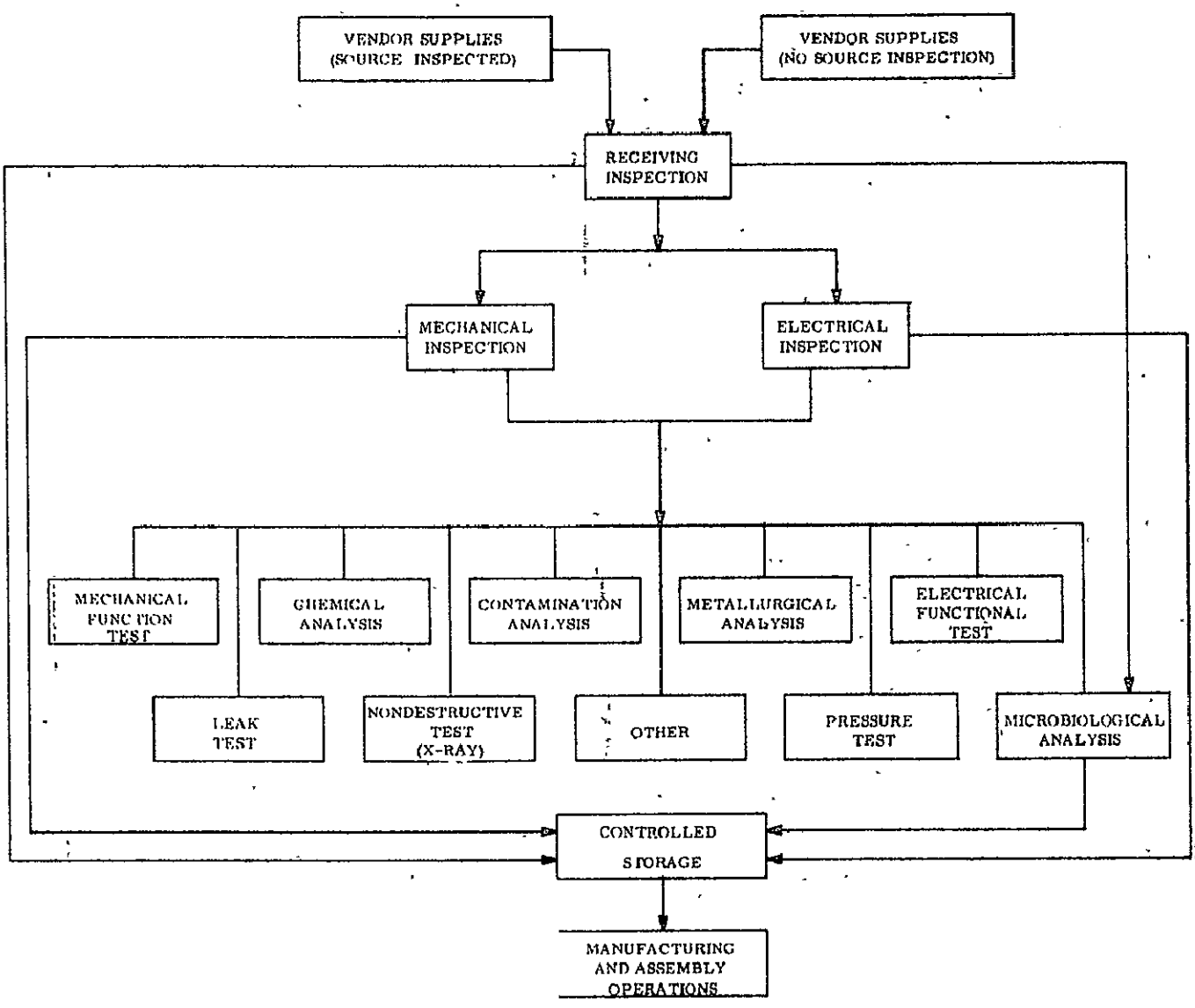


Figure 3-1. Receiving Inspection Flow Chart

be determined. This can then be correlated with the over-all cycle requirements and a realistic schedule can be established.

Receiving inspection is responsible for ensuring that all specialized tests are run, including those not accomplished by the receiving inspection activity.

3.5 RECEIVING INSPECTION EQUIPMENT

Equipment capable of meeting the test, inspection, and analyses requirements, shall be provided, in accordance with the minimum quality requirements established by the particular program.

3.6 FACILITIES

Facilities in the receiving inspection area will be adequate to provide for the required inspections, tests, and analyses. The layout of the receiving inspection area is most important and should allow for separation of items according to their intended use, within the framework of mechanical and electrical items. These facilities will be in an area large enough to permit the smooth flow of equipment through the receiving inspection activity.

A receiving inspection area in support of the fabrication and processing of sterilizable spacecraft subsystem should meet the following requirements as a minimum:

a. Clean room(s) will be provided where requirements dictate the control of temperature, contaminants and dew point. This will permit the inspection and/or test of critical items without degradation of the item.

b. Laminar flow bioclean work station will be provided where requirements dictate inspection of decontaminated or sterile hardware.

c. Bonded areas will be provided for control of at least the following items: high performance, costly and scarce parts, intricate and guarded procedures, including specifications and drawings, and delicate and precision gages. The bonded areas can be used to separate Government-furnished equipment from contractor property. The bonded area will also be available for discrepant material storage.

d. A receiving dock will be provided that is strategically located and able to handle all incoming materials.

e. The electrical power necessary to perform the inspections and/or tests will be monitored, regulated power.

f. The receiving inspection area should be enclosed to ensure proper control of materials and the inspection and/or test cycle.

g. The work benches, work areas, unpacking, cleaning, and repacking areas should be designed and laid out to obtain the best results possible for in-and-out flow of items through the receiving inspection operation.

h. Handling equipment to meet the requirements of moving hardware about the contractor's receiving inspection activity.

i. A packaging area in receiving inspection will provide for unpacking and repackaging of hardware before and after inspection and/or test.

j. The packaging area will be able to handle packaging such as, but not limited to, the following:

   1. Lumber and plywood boxes
   2. Various wrapping papers
   3. Moisture and vapor-proof barrier (MIL-B-131C)
   4. Cellulose packaging material
   5. Polystyrene cushion material
   6. Packing materials suitable for ETO decontamination
   7. Corrugated containers
   8. Desiccant materials

3.7 DATA AND REPORT REQUIREMENTS

Data and report requirements in the receiving inspection activity will be concerned with the designated procedures for the collection, recording, coding, storage, and dissemination of measurement data, the reports necessary to document satisfactory or unsatisfactory conditions that may exist, and the corrective action to be requested and input to the Data System. The data and report requirements serve to support the documentation requirements contained in NASA Quality Publication NPC 200-2 (Reference 3-2).

The contractor shall maintain records of inspections and/or test data performed throughout the entire receiving inspection activity. These records will provide evidence that the required tests and inspections have been performed (on parts, components, subassemblies, etc.), and shall show identification, inspection and/or tests involved, number of conforming articles, number rejected, number of defects, and basic cause for rejection.

This data will be suitable in format, accuracy, completeness, and detail to permit analysis and easy retrieval. This data will cover both conforming and rejected items. When data or information are required to be recorded, the film, tape, or other media will be identified with the characteristic measured and any other necessary multiplying factors. When defective time or nonconforming articles are involved, the records will include the results of analysis and corrective action taken.

Narrative comments, recommendations, tabulations, or pertinent receiving inspection data and a summary of corrective actions will be compiled into a monthly Quality Status Report which shall be submitted to the procuring activity.

3.7.1 TEST DATA

Test data will be furnished in accordance with NASA Quality Publication NPC 200-2 and other applicable standards. This data will include all the trouble, failure, and other measurement data associated with receiving inspection of components, units, etc. All test data shall be examined, analyzed, and documented so that troubles uncovered in receiving inspection may be brought to the attention of the cognizant quality and design engineering organizations.

Typical test data reports should indicate, as a minimum, the following;

a. Indicators of design deficiencies

b. Corrective and preventive action information to various elements of the contractor's organization

c. Significant quality trends

d. Complete test history on all articles received

e. Subcontractor quality ratings and feedback information for design improvement

3.7.2 INSPECTION DATA

Trouble, failure, and quality data on every part and component shall be completely and accurately collected, processed, and disseminated for analysis to all pertinent areas within the contractor's organization and to the concerned suppliers. The data required will include that specified in this section and in Section 2.10.

An inspection report or other form will be prepared for all items processed by the receiving inspection activity. A copy of the report will be attached to all defective items and will remain with the item until the defect is corrected or the rework, if necessary, is scheduled and accomplished.

Copies of the report will be distributed to the cognizant areas to be used in scheduling rework, preparing failure reports, accumulating reliability data, updating components lists, etc.

The report information will be compiled, computerized, and disseminated to cognizant personnel within the organization on a required, as requested, or regular basis.

3.8 RECEIVING INSPECTION OPERATIONS

The receiving inspection operations normally performed in support of the manufacture and checkout of an assembled stage are described herein. The objectives and requirements of each operation are included. All of the operations are not performed on every part or component, but they are applied as deemed appropriate. Because of the magnitude of materials, parts, components, etc., which pass through receiving inspection, it is impractical to attempt to describe all of the tests which are performed as a part of receiving inspection; however, the objectives required of the main categories of inspections are provided.

3.8.1 IDENTIFICATION

3.8.1.1 Objectives

The objective of the identification task is to control the identities of all components, hardware, and materials which are received by Receiving Inspection.

3.8.1.2 Requirements

The contractor shall establish and maintain an inspection stamp control system that will include, but not be limited to, the following:

a. All receipts at the contractor's plant will be clearly identified, and this identity will be maintained throughout the receiving activity cycle in order that items procured under NASA contract may be readily recognized. This requirement does not cover commercial or off-the-shelf material common to other projects, unless specified by contract. Raw materials will be identified at the receiving activity, and this identification will be maintained either on the fabricated article or on records traceable to the fabricated articles. All purchased articles released from the contractor's receiving inspection will be clearly identified to indicate conformance or rejection.

b. Stamps, decals, etc., will be designated to identify that the articles have undergone receiving inspection and/or tests. Articles that have been rejected or are being held for MRB*action need not be stamped, but the reject or withhold stamp will be applied to the hold tag or other documentation as appropriate.

c. Each stamp will be traceable to the individual responsible for its use, and records will be maintained to identify individuals with specific inspection or test stamps.

d. Stamps indicating that inspections have been performed will be applied directly to conforming articles, unless this is impractical because of physical limitations of the article. In this case, stamps should be applied to tags, cards, labels, etc., attached to individual articles as practical.

e. Stamp designs will not resemble Government Inspection Stamps. Ink should not be biologically nutritive

3.8.2 VISUAL ANALYSES

3.8.2.1 Objectives

The objective of the visual analysis task is to assure that all incoming hardware and materials arrive with no physical damage and that each item is properly identified and packaged.

*Materials Review Board

3.8.2.2 Requirements

To accomplish these objectives, the receiving inspection activity will visually inspect, but will not be restricted to, the following items:

a. Shipping containers for transit or handling damage

b. Hardware or materials for improper handling or packaging

c. Hardware or materials for proper workmanship, nicks, scratches, cracks, dents, tool marks, discoloration, or any other defects that may render the items unsuitable for the intended use

d. Proper documentation and paper work as required

The activity will document any discrepancies on the report prescribed in Section 3.7.2, "Inspection Data." Procedures will be established for handling material which has been damaged.

Each part and its shipping container will be visually inspected and identified in an established and uniform method of inspection.

3.8.3 DIMENSIONAL ANALYSES

3.8.3.1 Objectives

The objectives of dimensional analysis are to assure that the dimensions on all incoming hardware and materials match the dimensions on the drawings which were specified by the purchase order.

3.8.3.2 Requirements

Detailed receiving inspection planning will be accomplished in order to point out the critical areas of any items to be inspected.

The format to be used for dimensional analysis will point out the dimension to be measured and the tolerance allowed, the drawing, and location and the type of measuring equipment to

be used. Purchase order requirements, catalogs, drawings, and specifications will be researched to determine the dimensions to be inspected.

All critical dimensions will be inspected to the listed dimensions on the inspection instructions. These dimensions will not be construed as the only dimensions to be checked. The remaining drawing requirements will be checked on a frequency basis which is sufficient to assure that the parts comply with the specifications and drawing requirements.

3.8.4 NONDESTRUCTIVE TESTING

3.8.4.1 Objectives

The objectives of nondestructive testing are to obtain quality verification when other inspection is impractical or inadequate.

3.8.4.2 Requirements

In order to accomplish these objectives, at least the following methods, when necessary, will be used:

a. X-ray

b. Microscope

c. Fluoroscope

d. Pressure

e. Leak

f. Magnetic particle

g. Xyglo

h. Ultrasonic

i. Microbiological assay

When these or similar inspection methods are necessary, sampling plans can be used if they are in accordance with Program Requirements.

These tests can be accomplished within the contractor's facilities or in any approved subcontractor laboratory.

Proper documentation of these tests will be maintained by the contractor and will be made available to the cognizant NASA representative.

3.8.5 PHYSICAL OR CHEMICAL PROPERTIES ANALYSIS

3.8.5.1 Objectives

The objectives of the physical or chemical properties analysis are to verify that the materials have the properties specified by the procurement document.

3.8.5.2 Requirements

Chemical and physical testing will be used when necessary to verify quantitative, qualitative, and/or physical properties of the material or article. When the nature of the material or article does not lend itself easily to assuring the receiving inspection activity that the complete quality requirements are met, chemical and physical tests as necessary will be used to verify quality requirements. Test specimens may be required with purchased articles for tests.

3.8.6 STERILITY AND CONTAMINATION ANALYSES

3.8.6.1 Objectives

The objective of the sterility and contamination analyses is to verify that the materials and supplies conform to the specifications, standards, and other sterility requirements.

3.8.6.2 Requirements

Contamination and sterility verifications will be used when required to verify the biological

load of received materials and supplies. Sterile hardware and supplies do not really lend themselves to normal receiving inspection because any break into the protective package increases the probability of recontamination. Thus, sterility will normally be verified through vendor certifications, vendor surveillance, and controlled samples. The microbiologist will process controlled samples with bioassays to verify sterility of the biological test supplies such as agar, petri dishes, etc. and any contamination; i.e., nonconformance will be reported to receiving inspection at the time of such inspection.

3.8.7 DESTRUCTIVE TESTING

3.8.7.1 Objectives

The objectives of destructive testing are to determine that (1) the design limits and performance parameters have been met by testing a representative sample to destruction, (2) safety requirements have been met by testing a representative sample to destruction, and (3) the point of failure compares reasonably with the predicted value. In some cases, the objectives of destructive testing may be the investigation of failures, unsatisfactory conditions, and/or problem areas.

3.8.7.2 Requirements

Qualitative and quantitative data selected from destructive testing shall be made available upon request to the procuring activity. Destructive tests include, but are not limited to, the following:

a. Tension testing

b. Compression testing

c. Flexural testing

d. Transverse bending testing

e. Bend testing

f. Direct-shear testing

g. Torsion testing

h. Notched-bar impact testing

i. Hardness testing

j. Fatigue testing

k. Wear (abrasion) resistance

l. Pulverizing (check for buried microorganism)

3.8.8 ELECTRICAL PARTS ANALYSES

3.8.8.1 Objectives

The objectives of the electrical parts analyses are to assure that all electrical parts have acceptable electrical characteristics and that they will perform the function for which they are intended.

3.8.8.2 Requirements

In order to meet these objectives, the following requirements will be met:

a. All electrical parameters will be tested.

b. Other design characteristics will be checked.

c. All functional requirements will be tested.

3.8.9 MECHANICAL PARTS ANALYSES

3.8.9.1 Objectives

The objectives of the mechanical parts analyses are to assure that all parts will perform the functions which have been specified.

3.8.9.2 Requirements

All mechanical parts will be inspected visually and measurements and tests will be conducted as required to assure satisfactory quality. These measurements and tests may include a combination of inspection, nondestructive testing, destructive testing or electrical testing and will be conducted in accordance with procedures.

All mechanical parts will be tested at the contractor's plant. The contractor's receiving inspection function will verify that the specifications called for are met and the item can perform in the area of its intended use.

3.8.10 CONTROL OF DOCUMENTATION

3.8.10.1 Objectives

The objectives of documentation control are to ensure that all prerequisite documentation meets the requirements of a control system.

3.8.10.2 Requirements

The requirements of this system will be provided by the contractor to ensure control of all documents affecting the quality program and incorporation of changes throughout the receiving inspection activity. These documents include quality control procedures, specifications, procurement documents, engineering notices, and any similar documents. These documents will be distributed to the proper points and at the proper times in order that all test and inspection will be accomplished in accordance with the latest applicable documents. The system will also provide (1) for the prompt removal of all obsolete documentation from operating areas and (2) that quality personnel review all changes to determine their effect upon the quality of the fabricated articles and their effect on quality plan for the receiving activity.

The contractor will clearly define the effectivity point of all changes, except those which affect only presentation of information on a document and do not affect materials, fabrication, or performance. The contractor will assure that changes are accomplished on the affected

articles at an appropriate point, and that the changed articles are appropriately marked or identified and applicable documents are revised accordingly. Provisions will be made for adequate and timely inspection and test of all changed articles.

3.9 REFERENCES

3-1 "Space Vehicle Stage Analysis and Checkout Guidelines," NASA, George C. Marshall Space Flight Center Publication SR-QUAL-64-13, May 1964.

3-2 "Quality Program Provisions for Space System Contractors," NASA Quality Publication NPC 200-2. April 1962.

SECTION 4
ASSEMBLY AND CHECKOUT

SECTION 4
ASSEMBLY AND CHECKOUT

4.1 INTRODUCTION

This section covers the quality assurance philosophy and requirements for the assembly and checkout of a spacecraft to be sterilized by heating. The basic philosophy followed in these procedures is (1) piece parts will be fabricated by conventional (nonbioclean) methods; (2) piece parts will be decontaminated or sterilized before their use in higher subassemblies; (3) these subassemblies will be fabricated using special procedures usually not requiring clean room assembly; (4) major assemblies will be fabricated in clean rooms if the complexity warrants the control; and finally (5) spacecraft will be assembled in a bioclean room. The pyramidal or building block philosophy to testing and checkout will be utilized; i.e., each level of assembly will be checked through a series of rigorous and comprehensive tests before being assembled into the next higher assembly. At several points in the test and checkout phases and before assembly into the next high assembly, the hardware will be biologically assayed and the results compared to those predicted by the biological burden accumulation math model. If those predicted levels are exceeded, then the hardware will be decontaminated and/or other disposition will be made by the Contamination Review Board (CRB, see Section 2.12).

In keeping with the basic philosophy of this Manual, normal aerospace procedures will not be discussed except where necessary for clarification. The basic philosophy of fabrication analysis requires analyses of new materials, surveillance and control of manufacturing processes and environments, and an inspection of hardware. This philosophy is unchanged for fabrication of a spacecraft to be sterilized by heating. This fabrication analysis consists of thorough inspection of the completed part or item, a close monitoring of the fabrication operation, a check of the materials used, an analysis of the required environmental conditions, and, in some instances, production samples and subsequent destructive testing of these samples. Subassembly, assembly and end-item checkout can be accomplished in an expedient manner only if the fabrication and associated testing has been properly performed.

Because of the complexity and expense of large spacecraft, a thorough checkout of all components and subassemblies must be performed before incorporation into the spacecraft. This production testing is necessary to ensure that adequate manufacturing procedures were utilized to produce an acceptable component or subassembly, and that no degradation has occurred. This also minimizes cost and test time required on the assembled spacecraft by assuring that the subassemblies have been correctly manufactured and assembled. It permits test and analysis to be performed which cannot be performed at the next higher assembly. Thus, the checkout of the assembled spacecraft can proceed without being complicated or delayed by problems which could have been solved more expeditiously at the subassembly level.

The type of assembly facility, the clean room status of major test facilities, and the need for such facilities will be determined by the project management and the NASA Planetary Quarantine Officer at the time such activities are planned. Presently, it appears that major systems tests can be performed in conventional facilities with personnel controls and controlled handling and packaging. This implies that, whenever possible, systems tests are performed in clean rooms, but that conventional facilities can also be used. Personnel controls necessary for such activity include the prohibition of bare-hand contacts, reduction of number of people in contact with spacecraft, and similar safeguards. Controlled packaging includes complete coverage of spacecraft with plastic sheets before leaving clean room and removal of this cover only as required by test. Complete removal requires proper handling of plastic cover if reuse is contemplated (Ref. 4-6).

4.2 GENERAL OBJECTIVES

The guidelines contained in this section are intended to aid in achieving the required reliability of the spacecraft systems. In order to avoid excessively long sterilization periods which may adversely affect the reliability of the space vehicle, it is necessary to perform assembly and test of the spacecraft in a manner which will result in a low biological population before terminal sterilization. This requirement fundamentally affects all manufacturing, assembly, and test operations, thus affecting associated quality assurance requirements. Figure 4-1 shows a typical flow plan as used by JPL (Reference 4-7).

The basic objective of this section is to provide guidelines to the additional quality assurance

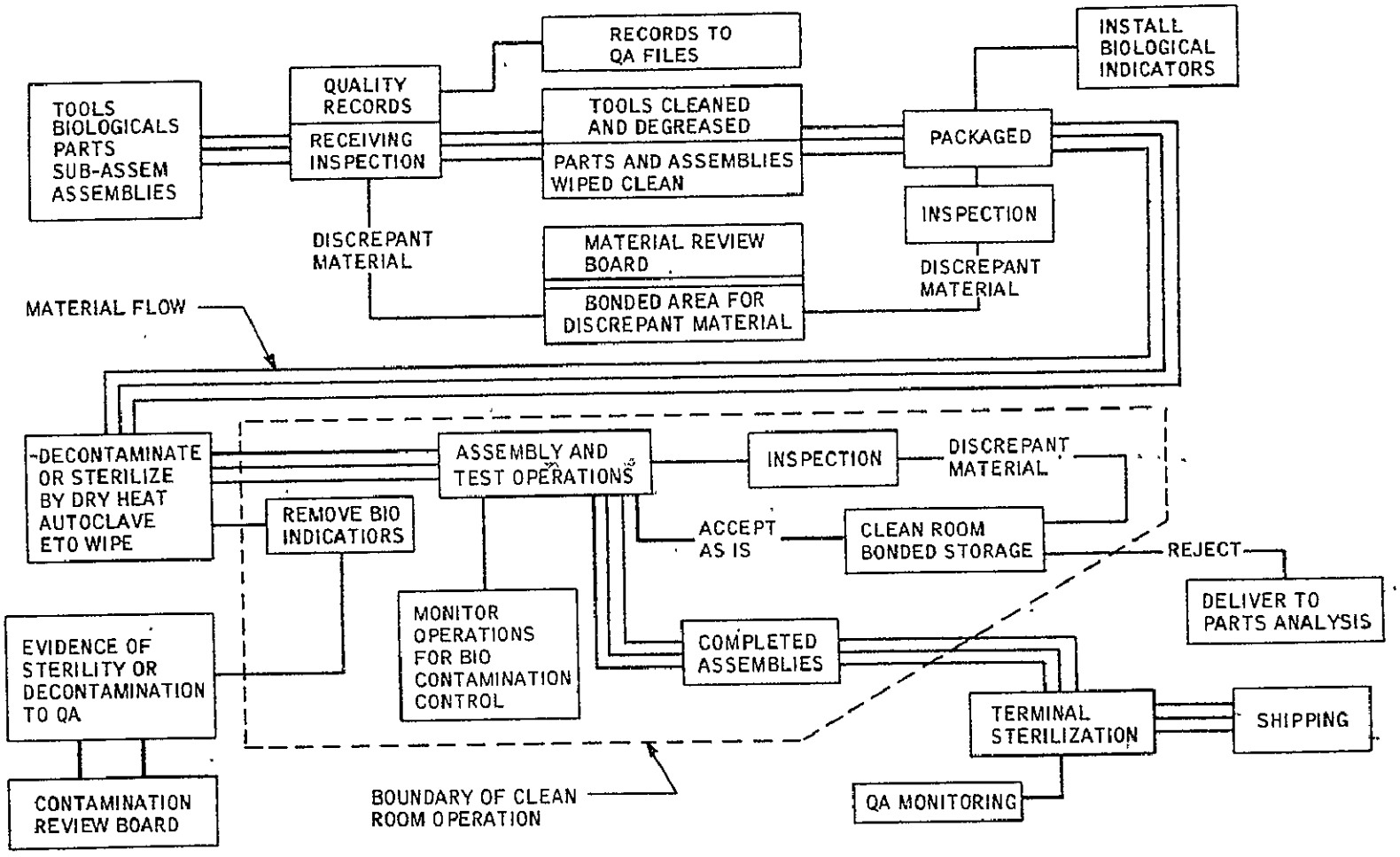


Figure 4-1. Typical Hardware Flow Plan

activity required for the assembly and test of a spacecraft to be sterilized by heating. It is assumed that the quality requirements of NPC-200-2 (Reference 4-2), SR-QUAL-64-13 (Reference 4-3) or equivalent are applicable, but need to be supplemented by the material contained in this Manual.

The guiding consideration in developing quality assurance procedures for the manufacture and assembly of sterilizable spacecraft is to introduce bioclean procedures as late in the assembly flow as possible, consistent with keeping the biological population at a sufficiently low level. The advantages of these guidelines are:

a. Maximum use of conventional aerospace procedures

b. Reduction in the number of people and organizations that must employ bioclean procedures

c. Shortening of the time span during which the biocleanliness of parts must be protected

d. Reduction in the number of tests to be performed on bioclean hardware

e. Reduction in cost

4.3 GUIDELINES

The general guidelines contained in this Section are intended to supplement those presented in nonbiologically controlled assembly and checkout procedures such as SR-QUAL-64-13 (Reference 4-3). Whenever specific guidelines are not provided, the philosophy of approach expressed in Sections 1, 2, and 6 of this Manual shall be deemed sufficient for guidance unless specific NASA policies and procedures exist.

The microbiological procedures of Reference 4-4 and standard operating procedures covered in Reference 4-5 as well as in Section 6 of this Manual shall be considered guidelines. When a specific program is established, detailed procedures, samples of which are shown in

Section 6, must be established and controlled. The functional reliability and microbiological control must be analyzed continually to achieve a suitable balance of acceptable quality procedures in the assembly and checkout of hardware.

Consideration shall be given to the reasons for assembly analysis. The mere ability of an item to perform a function is not the criterion for acceptance. Ability to perform its function when required and in the proper mode is the important item. Thus, engineering evaluations of the test results are required in conjunction with biological contamination control.

Visual monitoring of activities shall be conducted as described in Section 2.12.4 utilizing inspectors and closed circuit television. When a question of a contamination violation occurs, the following procedures apply:

a. All test data obtained during assembly analysis and checkout must be recorded and adequate records of this data must be maintained. Data obtained shall be used to form a testing history of each assembly. Data processing will be organized to the maximum extent to ensure that the data is available and utilized in the preparation of required reports.

b. Vendor data will not be accepted in lieu of testing.

c. Components utilized in major assemblies must be accompanied by their documentation and certification.

d. Testing shall be performed with adequate lead time to allow for microbiological assay completion.

e. A complete log of all events and defects or violations must be maintained to assure an adequate input to the data bank. This is in addition to a. above.

f. The procedures and limitations of clean room facilities must be observed and considered in any assembly and test plans.

g. The accessibility of major assemblies before, during and after test for the purpose of microbiological assays shall be reviewed with the microbiology team before start of a major assembly or test.

h. Whenever the spacecraft/lander or any of its subsystems are not actively worked upon, it is desirable to cover the surfaces with clean (sterile) polyethylene or similar films to prevent fallout accumulation, personnel contact and other sources of contamination.

i. When work is being performed on the spacecraft, those portions which are not required for access shall be covered with clean (sterile) films to prevent contamination.

j. Personnel procedures must be observed. They are discussed in Section 4.6.

4.4 RECOMMENDED PROCEDURES

The maintenance of particulate and biological cleanliness at the system level depends on the proper cleaning and packaging of the component and subsystems. As the assembly proceeds, the degree of cleanliness can degrade because of processes and handling. In order to eliminate or at least reduce the microbial burden buildup, detailed procedures, bioassay monitoring and contamination preventing safeguards are required. The types of subsystems and components likely to create the most difficult problems are those used for the storage, transmission and utilization of gases and liquids, electromechanical equipment, and certain electrical or mechanical subsystems.

4.4.1 PNEUMATIC AND HYDRAULIC SYSTEMS

The end use of this pneumatic or hydraulic hardware necessitates a higher order of particulate cleanliness than many other types of hardware, thus the additional requirements imposed by sterilization can be minimal, depending on the fluids, method of charging of a system and insertion prior to or after terminal sterilization. System cleaning is generally limited to gas purging with nitrogen because organic solvents attack the O-ring lubricants. Because nitrogen purging, by itself, is not very effective in reducing the biological load, contamination of assembled system must be avoided. Hot, dry nitrogen purge combined with vibration has been found to reduce significantly the amount of contamination and should be used if required.

Typical hardware for the containment and control of gases and fluids includes tubing, fittings, valves, regulators, nozzles, tanks, and filters. With the exception of the tubing, tanks, and fittings, these components are normally cleaned, assembled, tested, and packaged in a controlled environment.

The handling of fluids and fluid subsystems for a spacecraft to be sterilized by heating is an area in which considerable developmental work is required. For example, the insertion of sterile fluids into a previously sterilized system without introducing viable organisms still is a problem area. The use of fluid filtration devices without risking back-contamination as well as the choice of a suitable filtration method itself also need further work. These items must be considered by a potential planetary lander contractor.

In order to show a baseline requirement the following is provided. In the conduct of operations the work station, fixtures, etc., should be decontaminated by wiping with a disinfectant. Using decontaminated fluids for test will also aid in maintaining a low biological load. The following hydraulic system checkout and analysis procedure (Sections 5.10.2 through 5.10.2.2 from SR QUAL-64-13, Reference 4-3) shows an example of the "normal" requirements.

"5.10.2 HYDRAULIC SYSTEM

Hydraulic system testing medium and all components required to contain pressures will be completely checked. Cleanliness level of the testing medium must be controlled to avoid contamination of components to be tested with the medium. Monitoring of components contamination will also be conducted. All components (and their mating surfaces) must be leak and functionally checked to assure their capability to fulfill their test and mission requirements.

"5.10.2.1 Fluid Analysis

"5.10.2.1.1 Objectives

The purpose of these tests is to determine for control, the level of particle contamination in clean room atmospheres, compressed gases, and hydraulic fluids utilized for testing purposed in hydraulic subassemblies. Particle contamination in these fluids can cause contamination in components tested and subsequent failure of the components or system to function properly.

"5.10.2.1.2 Requirements

The following requirements will be met:

a. A blank sample count of contamination will be conducted on test equipment and test media before any tests are conducted.

b. Test equipment will be cleaned using flowing filtered solvent after each test is completed.

c. Clean room environment must be sampled in the vicinity of the test equipment twice daily. Results must be recorded and plotted for comparison.

d. Clean room envoronment contamination level limits will be defined specified by the procuring activity.

e. All test equipment must be cleaned, assembled, and disassembled in the clean room.

f. All test equipment will be properly protected and stored in the clean room when not in use.

g. Sample connection points will be purged for a duration and rate applicable to the hardware being checked.

h. All particle counting will be 100 percent or absolute. Counts can result in misleading and incorrect particle tabulations and must not be used.

i. Compressed gas contamination level limits must be established and will not exceed the limits established by the procuring activity.

j. Results that indicate grossly contaminated systems and components will require disassembly and cleaning.

k. Hydraulic fluid and hydraulic components will be contamination tested for particles in ranges established by the procuring activity and compatible with system design requirements. Hydraulic fluid will be filtered in accordance with approved methods until a satisfactory cleanliness level is obtained.

l. A blank analysis will be conducted on all hydraulic fluid contamination test equipment before any tests are conducted. This will determine the amount of contamination being introduced by the test equipment.

m. Fluid to be tested will be obtained from reservoirs only after sufficient fluid has flowed through the outlet to insure that the fluid has not been contaminated by the reservoir outlet.

n. Fluid must be agitated thoroughly before a test to insure that all solid particles are in suspension.

o. If gross contaminations are encountered during hydraulic fluid tests, statistical methods may be utilized to determine contamination level.

p. Photographs may be employed to illustrate and emphasize certain samples when a permanent record is desired.

q. Hydraulic fluid contamination level specification must be established and must not exceed the limits established by the procuring activity.

"5.10.2.2 Functional Test

5.10.2.2.1 Objective

The purpose of these tests is to functionally check all components of the hydraulic system that must function under contained hydraulic pressures. These are tested both for functional capability and cleanliness.

"5.10.2.2.2 Requirements

The following requirements will be met:

a. All components will be inspected for protective coverings, certification of previous proof pressure test, and cleanliness.

b. Component fittings and flares will be inspected before and after testing to determine any damage which may have occurred during testing.

c. All filter elements will be inspected for deformation or other unacceptable qualities. Unacceptable elements shall be replaced.

d. Components will be leak checked and observed for deformation. Oil will be the working medium and test will be performed at working pressure. Adequate safety equipment and practices will be employed to protect against hazards associated with testing components under high pressure. All valves must be tested to determine cracking and seating pressure.

e. The possibility of internal leakage of all system valve seats, "O" rings, etc., must be checked.

f. Pumps will be checked for contamination, operating pressure, flow, rate, and leakage.

g. Hydraulic package assemblies will be functionally checked. Contamination, switch operation, relief valve operation, and pump operation will be monitored.

h. A leak check of all connections and mating surfaces in the hydraulic system will be conducted.

i. A clearance check will be made around the engine while moving the engine to see that no obstructions prevent its full travel.

j. A step response test to check the rate of travel of the actuator system will be conducted.

k. A position linearity check of the command signal versus the actuator position is required."

4.4.2 ELECTROMECHANICAL EQUIPMENT

Electromechanical hardware like motors, gyroscopes, tape recorders, instruments and antennas can normally be assembled and tested using standard practices; however, with additional control of personnel and handling facilities. In the case of bearings, lubricants provide an excellent site for bacterial growth, therefore, decontamination and sealed packaging are extremely important for such devices. Frequent bioassays and contamination data analysis are required.

4.4.3 ELECTRICAL SYSTEMS

Electrical components and subsystems such as printed circuits, modules, black boxes, relays, harnesses, etc., can generally be assembled and tested using standard aerospace practices with additonal cleaning and handling controls required in some cases. Electronic modules were found to be at satisfactory contamination levels by the additon of a disinfectant like phenol in rinse solution used in standard process. After fabrication and bench test, the modules should be stored in sealed packaging and handled with gloved hands. Also, the test equipment which comes in contact with the module should be disinfected before use. (Ref 4-1)

Electronic black boxes should be assembled at clean work stations, using decontaminated parts and gloves. After assembly, the black boxes should be stored and tested in sealed protective packaging whenever possible. Most tests can be performed with the electronic black box in the protective packaging if the package design is such that all interfaces are accessible. All mating and demating of the connecting harnesses should be performed through protective connectors (extension) which can be removed leaving the hardware connection clean. Vibration and acceleration testing, etc., can also be performed with the packaging intact. Other tests like thermal vacuum and acoustic noise may require the removal of the protective covering. When this is the case, the hardware should be protected by all personnel wearing protective clothing, gloves, face masks, etc. Standard bioassay requirements apply.

4.4.4 MECHANICAL SYSTEMS

The mechanical systems like the structure, honeycomb and pyrotechnic devices can be fabricated using normal practices and decontaminated by heat sterilization before use. Parachutes, on the other hand, must be fabricated using special handling and materials. Thus all handling of parachutes shall require additional controls and the test of the actual flight unit must be curtailed to prevent contamination.

Thermal systems such as thermal insulation, thermal coatings and heat shields require no special consideration. Normal fabrication techniques with subsequent decontamination will reduce the biological burden to satisfactory levels. Active thermal control systems require more stringent procedures. Most testing and analysis on these types of materials is normally performed using test samples and will have no effect on the contamination level of the finished product.

4.4.5 FINAL ASSEMBLY

Final assembly of heat sterilizable spacecraft currently requires a Class 100 clean room. Recent experience has indicated that comparable low contamination levels can be achieved in a less critical environment. All subassemblies will be decontaminated before being brought into the clean room. Quality assurance must obtain the microbiological spore strips from the decontaminated hardware and sumit them for analysis. No hardware can be installed on the vehicle until the biological load of that hardware is known and the results are compatible with those necessary at that point based on the mathematical model. Bioassays will also be taken at the interfaces at the time of installation. All functional and other tests which can be performed in this clean room should be performed there. Tests requiring special facilities like vibration, thermal vacuum, etc., will require that the spacecraft be transported to these test facilities. The spacecraft shall be packaged in a plastic covering and placed in a handling container before removal from the clean room. The plastic covering should remain intact whenever possible. In some test conditions it is necessary to remove this covering. Whenever the covering is removed, the environment around the spacecraft must be at least access-controlled. A cordon shall be established around the spacecraft and the area identified as "off limits" to unauthorized personnel. The covering should be reinstalled as soon as possible after the completion of the test activity. (Ref. 4-13)

Additional checkout and analysis will be required when the spacecraft is mated to the canister. This will be discussed in Section 5.

4.4.6 DOCUMENTATION

Records of all inspections, bioassays and test performed throughout the entire fabrication assembly and checkout process shall be maintained. The records of the inspections and tests performed will provide evidence that the required test, inspections and analyses have been performed. The records of the bioassay data and analyses will be entered into the data system and can be used to predict the total number of microorganisms on the spacecraft before terminal sterilization.

When a component or subsystem is received for testing, it must be accompanied by a record (travel card) showing the part number, serial number, nomenclature, manufacturer and status. This record shall have a stamp affixed to show that the component or subystem has passed all preceding inspections and the present contamination level. Also accompanying the component or subsystem should be the test data from any previous testing and any calibration curves.

If the hardware has previously been decontaminated, then the integrity of the packaging shall be checked before the unit is removed for assembly or test. Before assembly, biological assay samples (swabs) will be taken from the interface of mating surfaces.

After the testing is performed, the test data must be gathered and evaluated and the test results and dispostion reported to all interested parties. If the component or subsystem is rejected or contaminated, a nonconformance report must be generated. After the discrepancy has been determined and resolve, a report of this activity must accompany the unit back into the system.

Failure analysis will be conducted and a report issued on the component which fail to meet a critical specification including contamination or when the test data indicates faulty design. This report will include an evaluation of the failure and recommended corrective actions required to avoid further failures of this nature.

Such data should be compatible with the requirements of an integrated data storeage and retrieveal plan (data bank). The integrated data storage and retrieval plan will support the analytical functions associated with the evaluation of the test and biological data.

4.5 FACILITIES

The facilities will be designed to fulfill the requirements of the test, inspection and analysis program. Special faciliteis are required for the manufacture and assembly of bioclean spacecraft (References 4-8, 4-9). Foremost amoung these are controlled environment facilities; i.e., clean rooms, clean enclosures, and clean work stations. The monitoring of the control of these facilities will be the responsibility of the quality assurance operation.

Table 4-1 shows guidelines to achieve these cleanliness levels (Reference 4-9). Table 4-2 shows similar data for bioclean rooms (Reference 4-8). Clean rooms and enclosures are classified by the quantity of airborne particles that they contain per unit volume. Federal Standard 209a (Reference 4-9) classifies clean rooms by the number of particles 0.5 micron or larger present in a cubic foot of air. The particulate level and the number of airborne microorganisms must be controlled by filtering the incoming air and by limiting the generation of particles within the area.

The cleanliness levels of the final assembly facilities must be established and certified before flight hardware manufacturing operations may be performed in them. Table 4-3 summarizes recommended procedures.

The main source of contamination in a controlled environment is people. Thus, the access of unauthorized and untrained personnel to the work area must be limited and controlled. Contact with the human hand is a major source of biological contamination of hardware, and extensive precautions should be taken to eliminate as much of this contamination as possible (Reference 4-10). This can be achieved by careful design of tools and fixtures and by wearing sterile gloves and other protective garments (see Figures 4-2 and 4-3).

The success of a bioclean hardware program depends more on humans than on facilities, because man is the biggest generator of microorganisms on aerospace parts. It is therefore essential to reduce, as much as possible, the transfer of these organisms from humans to hardware. To achieve this goal, the observance of proper work habits and procedures is more critical than the construction of elaborate facilities.

The NASA Standard for "Clean Rooms and Work Stations for the Microbially Controlled Environment," NHB 5340.2 (Reference 4-8), issued August 1967 has been incorporated throughout this Section of the Manual. This NASA Standard establishes the cleanliness levels which are required before a facility can be certified. A bioclean room is defined by Reference 4-8 as any enclosed area where there is control over viable and nonviable particulates in air with temperature, humidity, and pressure control as required to maintain specified standards for the manufactured product.

The following tables and information present typical contaminant monitoring techniques and requirements for which quality assurance personnel will be responsible.

4.5.1 CLASSES OF CLEAN ROOMS

Guidelines for achieving different degrees of cleanliness in clean rooms are shown in Table 4-1 taken from Federal Standard 209a (Reference 4-9), and Table 4-2 covering microbiological cleanliness taken from Reference 4-8.

Table 4-1. Guidelines for Achieving Clean Room Classes (Ref 4-9)

		Class 100 (3.5)	Class 10,000 (350)	Class 100,000 (3500)
Use Existing Facilities	Nonlaminar and laminar flow rooms, tunnel, and downflow units.	a. All laminar grating flow rooms, clean work stations, and downflow units. b. First work locations in crossflow rooms and tunnel units will meet requirements.	a. Some nonlaminar flow rooms and clean work stations may meet requirements. b. Most areas in laminar crossflow rooms and tunnel units should meet requirements. c. All laminar grating flow rooms, laminar flow clean work stations, and downflow units will meet requirements.	a. Most nonlaminar flow rooms and clean work stations will meet requirements. b. All laminar-flow rooms, clean work stations, tunnel, and downflow units will meet requirements.
Upgrade Existing Facilities	Using laminar flow clean work stations, tunnel, and downflow units.	a. Area inside clean work stations. b. First work locations in tunnel units. c. Area inside downflow units will meet requirements.	a. Nonlaminar flow rooms with laminar flow clean work stations, tunnel, and downflow units may meet requirements. b. Most areas inside tunnel units should meet requirements. c. Area inside clean work stations and downflow units will meet requirements.	a. Poor quality nonlaminar flow rooms with laminar flow clean work stations, tunnel and downflow units may meet requirements depending upon ratio of recirculated filtered air to room volume. b. Area inside clean work stations, tunnel, and downflow units will meet requirements.
New Construction	1. Laminar flow clean work stations, tunnel, and downflow units. Used in controlled areas.	a. Area inside clean work stations and downflow units will meet requirements. b. First work locations in tunnel units will meet requirements.	a. Area inside clean work stations and downflow units will meet requirements. b. Most areas in tunnel units should meet requirements.	Area inside clean work stations, tunnel, and downflow units will meet requirements.
	2. Laminar flow clean work stations, tunnel, and downflow units. Used in controlled areas.	a. Area inside clean work stations and downflow units will meet requirements. b. First work locations in tunnel units will meet requirements.	a. General area may meet requirements depending upon ratio recirculated filtered air to volume of area. b. Most areas in tunnel units should meet requirements.	a. General area will normally meet requirements, depending upon ratio of recirculated filtered air to volume of area. b. Area inside clean work stations, tunnel, and downflow units will meet requirements.
	3. Laminar cross-flow type rooms.	First work locations will meet requirements.	Most areas in room should meet requirements.	All areas in room will normally meet requirements
	4. Laminar flow grating floor type rooms.	Entire room work area will normally meet requirements.	Entire room work area will normally meet requirements.	Entire room work area will normally meet requirements.

Notes:
1. Laminar flow work stations include clean room benches and clean air exhaust hoods
2. Tunnel units indicate laminar crossflow facilities, open on one end to exhaust into surrounding area
3. Downflow units indicate vertical flow curtained modules

FOLDOUT FRAME

FOLDOUT FRAME

Table 4-2. Guidelines for Achieving Bioclean Room Cleanliness Classes (Reference 4-8

	Use Existing Facilities	Upgrade Existing Facilities	New Construction				
	Nonlaminar and laminar flow rooms, tunnel, downflow units, and microbial barrier systems.	Using laminar flow bioclean work stations, tunnels, downflow units, and microbial barrier systems.	Laminar flow bioclean work stations, tunnel, downflow units, and microbial barrier systems used in uncontrolled areas.	Laminar flow bioclean work stations, tunnel, downflow units, and microbial barrier systems used in controlled areas.	Laminar cross flow type rooms	Laminar flow grating floor type rooms.	Germ-free environmental room
Class 100 (3.5)	1. All laminar flow grating floor rooms, bioclean work stations, downflow units, and microbial barrier systems. 2. First work locations in cross flow rooms and tunnel units will meet requirements.	1. Area within bioclean work stations. 2. First work locations in tunnel units. 3. Area inside downflow units. 4. Area inside microbial barrier system will meet requirements.	1. Area within bioclean work stations downflow units, and microbial barrier systems will meet requirements. 2. First work locations in tunnel units will meet requirements.	1. Area within bioclean work stations, downflow units, and microbial barrier tems will meet requirements.	First work locations will meet requirements	Entire room work area will normally meet requirements	Entire room work area will meet requirements
Class 10,000 (350)	1. Some nonlaminar flow rooms and bioclean work stations may meet requirements. 2. Most areas in laminar cross flow rooms and tunnel units should meet requirements. 3. All laminar flow grating floor rooms, laminar flow bioclean work stations, downflow units, and microbial barrier systems will meet requirements.	1. Nonlaminar flow rooms with laminar flow bioclean work stations, tunnel, downflow units, and microbial barrier systems may meet requirements. 2. Most areas inside tunnel units should meet requirements. 3. Area inside bioclean work stations, downflow units, and microbial barrier systems will meet requirements.	1. Area inside clean work stations, downflow units, and microbial barrier systems will meet requirements. 2. Most areas inside tunnel units should meet requirements.	1. General area may meet requirements depending upon ratio of recirculated filtered air to volume of area. 2. Most areas inside tunnel units should meet requirements.	Most areas in room should meet requirements.	Entire room work will normally meet requirements.	Entire room work area will meet requirements.
Class 100,000 (3500)	1. Most nonlaminar flow rooms and bioclean work stations will meet requirements. 2. All laminar flow rooms, bioclean work stations, tunnel, downflow units, and microbial barrier systems will meet requirements.	1. Poor quality nonlaminar flow rooms with laminar flow bioclean work stations, tunnel, downflow units, and microbial barrier systems may meet requirements depending upon ratio of recirculated filtered air to room volume. 2. Area inside bioclean work stations, tunnel, downflow units, and microbial barrier systems will meet requirements.	Area inside bioclean work stations, tunnel downflow units, and microbial barrier systems will meet requirements.	1. General area will normally meet requirements depending upon rate of recirculated filtered air to volume of controlled area. 2. Area inside bioclean work stations, tunnel, downflow units, and microbial barrier systems will meet requirements.	All areas in room will normally meet requirements.	Entire room work area will normally meet requirements	Entire room work area will meet requirements

Notes:
1. Laminar flow work stations include bioclean room benches and bioclean air exhaust hoods.
2. Tunnel units indicate laminar cross flow facilities, open on one end to exhaust into surrounding area.
3. Downflow units indicate vertical flow certained modules.
4. Microbial barrier systems indicate absolute containment enclosure.
5. Germ-free environmental room indicates a sterile room in which the operations are performed remotely or with the personnel contained in an externally ventilated barrier suit.

FOLDOUT FRAME 1

FOLDOUT FRAME 2

Table 4-3. Certification of Final Assembly Facilities

ITEM	PROPERTY	TECHNIQUE OR INSTRUMENT	REQUIREMENT	SAMPLING	REFERENCES
Air	Total Particulate Contamination	Light scattering principle	Maximum 100 particles/ft^3 (3.5 liters) ≥ 0.5 micron	As required by the contractual document	NASA Standard NHB 5340.2 5.1.1 and 5.2.1
	Viable (Microbial) Contamination	Volumetric samples	Maximum 1 organism/10 ft^3 (0.035/10 liters)	• Minimum of 3 samples after installation of filters and prior to assembly operations on flight hardware • Samples to be taken at working level, using 1 cfm for 60 minutes • Incubation at 32°C for 72 hours	NASA Standard NHB 5340.2 5.1.1 and 5.2.1 NASA Standard NHB 5340.1 Procedure No. 1
	Velocity	Velometer	90 ± 20 ft/min minimum average		Federal Standard 209a, 40.2.12 NASA Standard NHB 5340.2, 4.2.12
	Temperature	Thermometer or thermocouple	Average to be within range of 67°F to 77°F ± 5°F in less critical areas ± 0.5°F in critical areas		Federal Standard 209a, 30.2 NASA Standard NHB 5340.2, 30.2
	Relative Humidity	Humidistat	45% maximum		Federal Standard 209a, 4.7 NASA Standard NHB 5340.2, 30.3
HEPA** Filter Banks	Leaks	Scan HEPA** filter surface using an aerosol smoke photometer and DOP	An aerosol photometer reading ≥ 0.01% of the upstream smoke is considered a leak and must be sealed off.	• Sample each filter separately prior to installation • Scan the filter frame after installation of filters	Federal Standard 209a, 50.1 NASA Standard NHB 5340.2, 501.1
Surfaces	Viable Contamination	Not Specified	Not Specified	Not Specified	Not Specified
	Viable (Microbial) Contamination	1 x 2 inch settling strip, Rodac plate, Cotton swab	Maximum 1,200 organisms/ft^2 (12,000/M^2)	• 6 strips to be removed and assayed from each carrier tray per sampling interval • Minimum exposure per NASA management	NASA Standard NHB 5340.2, 5.1.1 NASA Standard NHB 5340.1, Procedure No. 1

*"*Clean Room and Work Station Requirements, Controlled Environment*," Federal Standard 209a, General Services Administration, August 10, 1966
**HEPA: High Efficiency Particular Air Filter Units

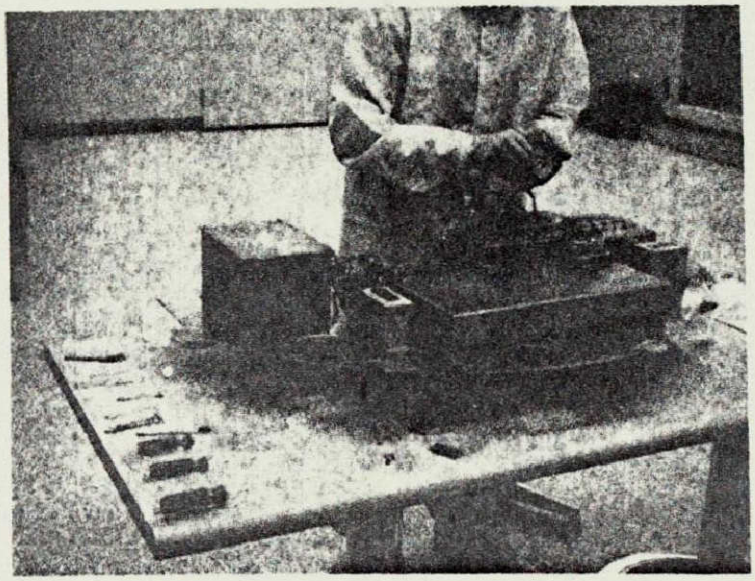


Figure 4-2. Bioclean Assembly and Tools

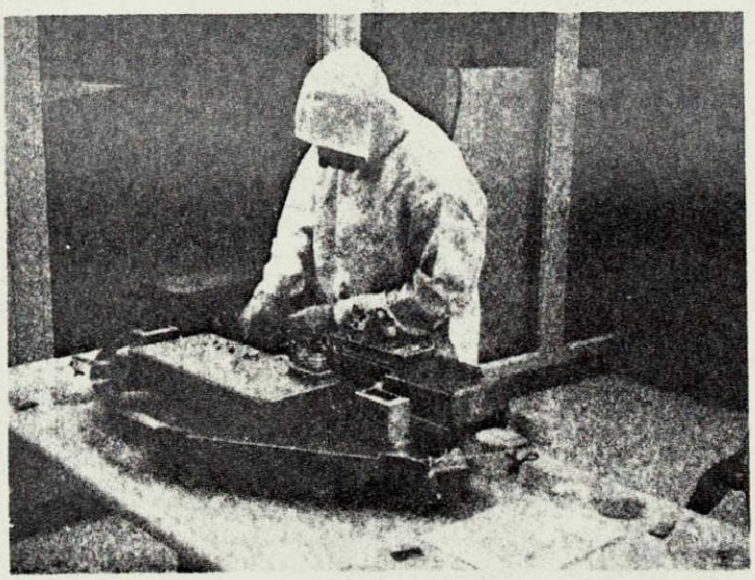


Figure 4-3. Bioclean Assembly

4.5.2 MONITORING TECHNIQUES

Clean rooms or clean enclosures used to prevent or reduce contamination must be continuously or intermittently monitored for airborne contaminants. Principal methods for monitoring particulates are shown in Table 4-4. Techniques for microbiological contamination monitoring are described in Reference 4-8 and summarized in Table 4-3. A major problem with biological monitoring is the time lag required for specimens to incubate before growth can be visually determined. This is not a problem with the devices shown in Table 4-4. Optimum placement within a room or enclosure is required to relate the measurements with actual room conditions.

Methods of monitoring the level of biological contamination of hardware during various stages of assembly and test are shown in Table 4-5.

Table 4-4. Airborne Contaminant Monitoring

Method	Principle	Type	Comments	Remarks
LIGHT SCATTERING	Light scattered by particles passed through a high intensity light beam is detected and converted to electrical pulses by a photomultiplier tube.		Produce the least physical effect on the particles themselves and has high sensitivity.	Particles are sized and counted Channels are individually scanned.
Particle Counters	Pulses corresponding to individual particles are electronically separated, sized and counted.	Instantaneous particle counting and sizing.	Excellent for analytical work where size and concentration versus instantaneous event desired. No qualitative data can be obtained.	All particles over a predetermined size are counted and totaled. Instrument is portable.
• Level Indicators	Pulses from photomulitplier are integrated to indicate an average level.	Continuous instantaneous dust level	Less expensive than light-scattering devices. Dust-level fluctuation versus time easily obtained. Ideal for continuous monitoring use.	Instrument utilizes forward scattering for maximum sensitivity.
VOLUME DISPLACEMENT	Particles suspended in an electrolyte are drawn through a small aperture. An individual particle displaces its own volume of fluid producing a resultant electrical pulse proportional to the particle size.	Instantaneous particle counting and sizing.	Gives true particle volume measurement. Some types of particles will be dissolved or altered when suspended in solution. Unsuitable for continuous monitoring of particle range from 0.7 to 200 microns.	All particles over a predetermined size are counted and totaled.
MICROSCOPIC	Collected dust is counted and analyzed by optical microscope.		Provides the best qualitative information for source identification. Requires trained operator and careful technique.	Any high-quality microscope may be used. Counting is made simpler and less tedious by using a projection-type microscope.
• Setting Collection	Dust is allowed to settle on some collecting and counting surface.	Continuous sample, cumulative.	Sees only settled-out dust. Requires long sample time with time lag in obtaining results	
• Filtration Collection	Dust is strained from air sample by a membrane filter.	Grab sample, cumulative	Provides a quick sample. Produces excellent quantitative and qualitative data. Monitors particles 5 microns and larger.	Filters, holders, pumps, and associated equipment are available. Filters may be viewed with incident light or rendered transparent by different liquids.
• Impaction Collection	Dust-laden air is forced through a small aperture at near-sonic velocity. By placing a collecting surface in the air path, the dust is separated out by inertial forces and caused to adhere on the collecting surface.	Grab sample, cumulative.	Provides quick sample. Method is most sensitive to one particular size range, depending on orifice. Matter may be altered by forces involved.	Instrument contains impactor and counting microscope. Device takes very small sample Instruments provide a series of slits for maximum sensitivity over total size range.
• Electrostatic Precipitation Collection	Dust charged in a high-potential field is collected on metal surface of opposite polarity.	Grab sample, cumulative.	Requires short sample-time. Particles must be collected on metal surface. Requires high voltages (10 kv and over)	Dust is collected on the inside of a metal tube.
• Thermal Precipitation	Dust passed between hot and cold surface is caused to collect on cold surface for counting.	Continuous sample	Very low collection rate and low efficiency for large particles.	Collection rate 7.0 ml/min. Efficiency drops sharply for particles above 5 microns.

FOLDOUT FRAME 1

FOLDOUT FRAME 2

Table 4-5. Monitoring Techniques for Hardware Flow

Location	Monitoring Operation	Monitoring Technique	Number of Samples	Frequency of Sampling	Remarks
General Fabrication	No monitoring of biological contamination				
Subassembly	• Microbial levels in air in clean rooms and clean benches	Reyniers Slit Sampler	Not less than three	Once each month when work is in progress.	
	• Viable particle fallout on surface in all clean rooms and clean work benches	Fallout strips	Not less than 2 strip samplers	Once each month	
	• Viable particles on and in components	Surface sampling and sterility tests	Spot check of basic parts used in sub-assemblies		Subassemblies should be delivered for assay in the same package used to transfer the hardware within the manufacturing facility
Assembly, Test, and Checkout	• All operations	Visual		Continuous	
	• Decontamination procedures	Visual		Continuous	
	• Calibration of temperature time indicators and recorders	Standard		Spot Check	
	• Temperature-time records of heat and ETO procedures.			Daily	
	• Microbiological contamination of clean room air	Reyniers Slit Sampler	Three samples	At least twice each week	
	• Viable particulate fallout onto surfaces	Stainless steel strips	Six strips from at least three locations	Assayed twice weekly	Minimum exposure of strips should be one week.
	• Microbial contamination on clean room clothing	Not specified	From at least 3 garments, one each min.	Not less than once a week	Garments should be sampled as they become available. Use of them must await the results of the assay.
	• Spacecraft covers and other flexible film materials	Not specified	From at least 6 locations on each sheet		Assay must be performed before material is introduced into clean room unless sterilization will be accomplished by means of dry heat or autoclave.
	• Particles on and in components	Not specified	Approximately 10% of the basic parts (not subassemblies) shall be assayed		Quantitative levels on surface, and quantitative and/or qualitative interval
	• Microbial contamination on tools	Impression plate, swab, or total immersion			Number of samples and schedule to be established.
	• Microbial contamination on personnel	Not specified	Samples to be taken from cheek, chest, back, fore-arm, and palm and any other locations at any other times required by sterility control personnel or by the medical officers.	Not less than once a week	

Typical instruments for the monitoring of biological contamination are shown in Figure 4-4. The Andersen sieve sampler permits the determination of the size of the contaminants. The Reyniers slit sampler shows a time record of the occurrence of contamination. Both instruments draw in forced air streams and deposit the biological contaminants contained in them on nutrient plates which are subsequently incubated for 2 to 5 days. Fallout plates rely on the gravitational movement of microbiological particles, either directly on a nutrient plate (Petri dish) or on stainless steel plates which are subsequently rinsed off and the rinse incubated.

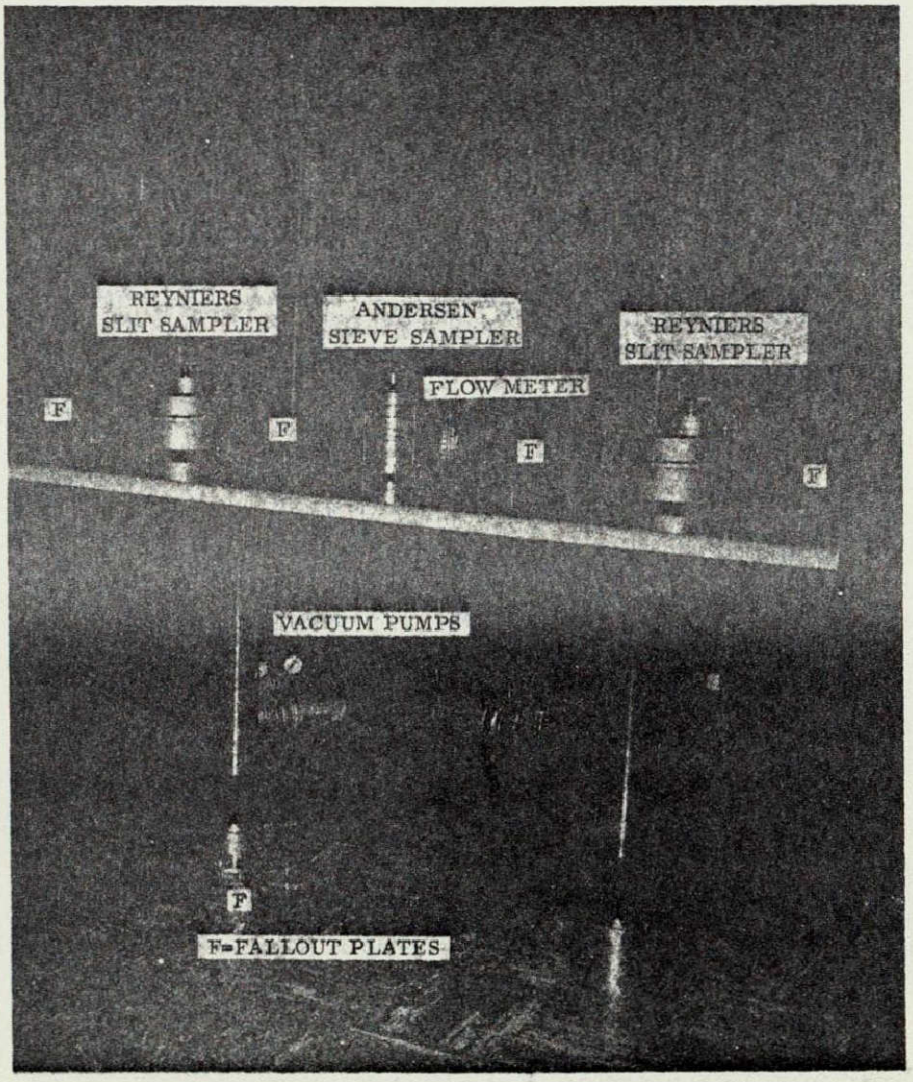


Figure 4-4. Instruments for Monitoring Contaminants

The following material taken from NHB 5340.2 (Reference 4-8), states some of the NASA Standard recommendations for environmental conditions in bioclean facilities.

"ENVIRONMENTAL CONDITIONS

"AIRBORNE PARTICLE COUNTING. Airborne particle concentrations, viable and non-viable, should be measured at representative locations in the bioclean room or work station. It is necessary to recognize that the differences between non-laminar, laminar airflow, and microbial barrier systems lead to different measuring techniques. For example, any contamination generated in non-laminar flow rooms or work stations tends to be diffused over the entire work area generally, thus airborne particle counts will be fairly uniform through the whole work area. Air samples therefore should be taken at work height level and in the general work activity areas.

"In laminar flow devices, however, any airborne contamination released into the work area will follow the air stream path toward the exit, therefore, contamination levels in these devices will vary to a marked degree from air cleanliness class 100 to the specific contamination level downstream of the dirtiest operation. Thus, in a laminar flow facility the sample of air should be taken from the air as it approaches the work activity area of interest. Particles count should be taken at work height level and in the general work activity areas.

"RECOMMENDED TEMPERATURE RANGES. Temperatures in the bioclean room should be maintained around a mean temperature of $72^{o}F$ ($22.2^{o}C$) for personnel comfort with the exception of those laboratories or work areas for which other temperatures may be necessary for control of stability of items being fabricated or tested or for micro-organisms control in which case the mean temperatures should be specified. Choice of temperature may be based on the desired die-away of vegetative microorganisms which, when humidity is held constant, is directly proportional to temperature. The temperature variation at the control point may range from $\pm 0.25^{o}F$ ($\pm 0.14^{o}C$) in the most critical operations to as much as $\pm 5.0^{o}F$ ($\pm 2.8^{o}$)."

4.5.3 STERILITY INDICATORS

The ultimate measure of success of a quality assurance program is the ability to deliver a sterile spacecraft. Sterility can never be measured directly. Only nonsterility (i.e., the presence of viable organisms) is measurable. The best indication of sterility is the lack of growth of microorganisms in culture of test samples taken from the item treated. This type testing may be destructive and, therefore, many items cannot be tested directly. Indicators which can be retrieved and tested are widely used as a substitute for testing

processed items. The indicators normally employed for sterility checks are processed simultaneously with the items being sterilized except for thermometers, thermocouples and other temperature-sensing instruments. A guide for the selection of an indicator consistent with the sterilization method used is presented below:

Sterilization Method	Indicator	Property Under Measure
Dry Heat or Moist Heat	• Thermometer • Thermocouple • Temperature sensitive - Tapes - Paints - Labels - Crayons - Ampules • Bacterial spore strips, ampules, and packets	• Temperature • Temperature • Temperature • Viability
Ethylene Oxide	• Chemical indicators • Spore strips	• ETO concentration • Viability
Peracetic Acid	• Spore strips	• Viability
Filtration	• Direct culture of filtrate	• Viability
Radiation	• Isotope counting devices • Sensitive chemicals • Bacterial cultures	• Dosage • Dosage • Viability

4.5.4 FACILITY MAINTENANCE

In order to make contamination control effective, all controlled environment facilities require a thorough cleaning and decontamination maintenance program. The experience of operators of large clean rooms with control of particulate matter shows that most janitorial services do more harm than good. It is to be expected that this is even truer for clean rooms which include biological controls. Therefore, periodic cleaning services should not be performed more often then necessary. The presence of janitorial personnel can be reduced by having daily cleaning of each work station performed at the beginning of each shift by the operators themselves.

During the performance of a pilot spacecraft bioclean assembly by General Electric (Reference 4-1), janitorial cleaning of the bioclean rooms was limited, and no degradation of cleanliness was observed over a period of 6 weeks. RCA, which operates the largest existing laminar downflow clean room at Lancaster, Pennsylvania (20,000 sq ft), has its operators wipe their work bench tops with deionized water; floors are mopped once a week, if required, with mops having monofilm fibers (only 40% of the floor consists of grating). Walls are spot cleaned when necessary, and there is no periodic cleaning schedule. The air flow is 50 ft/min, and the room averages 1.8 particles $> 0.5\mu/ft^3$ of air. This demonstrates the self-cleaning capability of laminar downflow facilities.

4.5.5 GLOSSARY

The following glossary taken from Reference 4-8 explains the most common terms used in connection with biologically controlled manufacturing and test facilities.

"AEROSOL. A suspension of ultramicroscopic solid or liquid particles in air or gas.

"DUST. Any powdered matter fine enough to be easily suspended in air or gas.

"NON-LAMINAR FLOW BIOCLEAN ROOM. A room characterized by no requirement for uniformity of airflow patterns and air velocities.

"NON-LAMINAR FLOW BIOCLEAN WORK STATION. A work station characterized by no requirement for uniformity of airflow patterns and air velocities but having specific requirements for control of viable particulates. This includes work stations which have constructed air exhaust or ports.

"LAMINAR AIRFLOW. Airflow in which the entire body of air within a confined area moves with uniform velocity along parallel flow lines.

"LAMINAR FLOW BIOCLEAN ROOMS. A room in which the laminar airflow characteristics predominate throughout the entire air space, with a minimum turbulence, and having specific requirements for the control of viable particulates.

"LAMINAR FLOW BIOCLEAN WORK STATION. A work station in which the laminar airflow characteristics predominate throughout the entire air space, with a minimum turbulence, and have specific requirements for the control of viable particulates.

"HIGH EFFICIENCY PARTICULATE AIR FILTER (HEPA). MIL-F-51068A specifies filters with minimum efficiency of 99.97% determined by the homogeneous Dioctyl Phthalate (DOP) method of air flows of 100% and 20% of the rated flow capacity of the filter. It is referred to as the "HEPA" filter.

"FILTER AIR. The air which issues directly from the "HEPA" filter.

"FIRST WORK LOCATION. The work location first in the path of the filter air.

"DYNAMIC AIR SAMPLING. The sampling of the air in the air space to obtain the number of airborne particulates and define those particulates carrying viable microorganisms.

"FALLOUT SAMPLING. The horizontal placement of sterilized strips in the air space for collection of depositied particulates which may have viable microorganisms and which have been airborne prior to deposition on the collection surface.

"MICROBIAL BARRIER SYSTEM. The protection system used to prevent microbial migration and contamination of a product with microorganisms.

"MICROORGANISMS. Microscopic plants or animals in seven principal groups called protozoa, true fungi, mold-like higher bacteria, true bacteria, spirochetes, rickettsiae, and filtrable viruses. "

4.6 PERSONNEL PROCEDURES

Rigid, yet workable procedures for the behavior of personnel inside clean facilities and near clean hardware must be established and observed. These procedures must then be rigorously enforced; otherwise, workers lose respect and tend to ignore all procedures which are not to their liking. A typical example of entrance and exit procedures during manufacture of electronic components in the JPL EASL facility is shown in Table 4-6 (Reference 4-11). Similar procedures will be required in bioclean assembly areas.

Table 4-6. JPL EASL Facility Entrance and Exit Procedures

Entrance

1. Enter door outside locker room and remove clean cloth from stack.
2. Thoroughly wipe top and sides of each shoe with this clean cloth.
3. Discard cloth in designated container.
4. Clean each shoe in shoe cleaner for a minimum of 20 seconds.
5. Enter locker room.
6. Clean finger nails.
7. Scrub hands to two inches (approximately) above wrist with pHisoHex soap and sterile brush for a minimum period of two minutes.
8. Clean shoes on vibration shoe cleaner.
9. Enter and turn on air shower.
10. Place hands over head and turn around slowly in air shower for a minimum air wash of 20 seconds.
11. Enter dressing room.
12. Don fresh, clean room laundered cap and smock.
13. Don breath deflector and obtain package of sterile rubber gloves.
14. Enter air lock and proceed through to hardware assembly area.
15. Don sterile rubber gloves and begin work.

Exit

16. Exit through Bioassay station.

Re-Entry

17. For re-entry to hardware assembly area, repeat steps 1 through 12. Steps 1 through 17 above Steps 1 through 17 above will be witnessed by QA Inspector. Any deviation will be noted.

NOTE

For maintenance and/or microbiological work in the laminar downflow room, these procedures do not have to be followed, provided the flight hardware is not present or is in a covered container. However, a cap and smock must be worn, and sterile gloves will be donned prior to entering the air shower from the locker room. For work in the dressing room, only sterile gloves need be donned prior to entering.

Janitors will not be required to follow these procedures; their procedure will be:

a. Use air shower

b. Don hat and smock

c. Use gloves that are normally used in the cleaning procedure.

The NASA Standard NHB 5340.2 (Reference 4-8) has listed personnel conduct guidelines, which are non-mandatory, but desirable. Some of these operational guidelines are shown as follows:

"Equipment cleaning and decontamination. All equipment should be cleaned and decontaminated before being passed into the bioclean environment by dusting, vacuuming, washing, dunking, or by suitable means, compatible with the equipment involved.

"Personnel covering. All personnel should wear lint-free, non-shedding garments in the bioclean area. Head covering which covers the entire head should be used to avoid part or component contamination by loose bits of hair or loose skin flakes.

"Cosmetics. Hand lotions, creams, or soap containing lanolin to tighten skin particles should be used as appropriate. Cosmetics and medication which may produce contamination should not be permitted. In particular, eye make-up, rouge, face powder, and hair spray should not be used and fingernail polish should be removed before entering the bioclean area.

"Smoking and eating. Under no conditions should smoking or eating be permitted in the bioclean area.

"Parts handling methods. Gloves, tweezers, or other mechanical barriers to prevent contact between skin and hardware should be used while working with or handling sensitive parts to avoid contamination of those parts by loose skin, microbiota, or natural skin oils. Solvent contact with hands should be avoided, as many solvents remove natural skin oils causing excessive "skin peeling" or flaking.

"Paper and writing materials. Paper should be limited to the non-shedding type or enclosed in a transparent non-shedding covering when used in the bioclean area. Only ball point pens should be used for writing. Lead pencils and erasers should not be permitted in the bioclean area.

"Custodial equipment. All equipment used to maintain the cleanliness of the bioclean area should be stored within the bioclean area in a manner which will prevent accumulation or dispersion of particulates or microbiota on the surfaces and reduce particulate shedding when used. Vacuum hoses, electric cables, and other flexible conductors should be stored on reels or racks off the floor of the bioclean area. Synthetic sponge mops should be hung so that the mop head does not touch the floor. Use of bristle brushes, steel wool, and other particle sheddding materials should not be permitted.

"Cleaning operations. Before being transported into the bioclean area, all parts, instruments, materials, and systems should be cleaned as required to prevent contamination of the room. To prevent direct transfer of contamination, constant surveillance of the established procedures for handling clean parts and assemblies is recommended. Particular attentions should be paid to cleaning operations that are performed in the bioclean room. Ultrasonic cleaners, spray rinses, and volatile immersion baths may release liquid droplets containing contaminants into the room air. The design of the cleaning equipment, and its location in the room should be selected to minimize this problem. Where practical, contamination producing operations should be located in adjoining areas, and the work should be passed into the bioclean room without cross contamination after the operation has been performed.

"Containers. Transport and storage containers should be made of low particle shedding materials. They should also have as rigorous a cleaning schedule as the parts or equipment. Care should be taken to ensure that containers used for transporting cleaned parts do not transfer contamination from surface to surface in the bioclean room."

In addition, Table 4-7 presents rules of conduct to be observed within a Bioclean Facility.

Table 4-7. Rules of Conduct Within a Bioclean Facility

Do's	Dont's
• Report any respiratory or skin ailments to the supervisor.	• Don't enter any bioclean work area with respiratory or skin ailments without approval.
• Follow all entrance and exit procedures.	• Don't omit any of the steps prescribed in the entry and exit procedures.
• Minimize the number and speed of motions to avoid air turbulence. This is particularly important in a non-laminar flow facility.	• Don't create air turbulence with unnecessary or hasty movement.
• Wear sterile gloves when handling bioclean hardware.	• Don't handle hardware with ungloved hands or with gloves that have been contaminated.
• Avoid contaminating sterile gloves	

Table 4-7. Rules of Conduct Within a Bioclean Facility (Cont)

Do's	Dont's
• Replace contamined gloves immediately.	• Don't contaminate sterile gloves by touching exposed parts of the body or other sources of contamination.
• Wear a mask or shield whenver the face is within approximately three feet of the hardware.	• Don't touch anything with the contaminated gloves.
• Wear garments as prescribed at all times.	• Don't cough, breath or sneeze on the hardware.
• Report any breach of the above rules to area supervisor.	• Don't open or remove garments within the bioclean area.
• Enter a bioclean area only when absolutely necessary.	• Don't allow broken rules to go unreported.
• Always obtain approval from the area supervisor before entering a bioclean facility.	• Do not enter a bioclean facility without need.
• Follow manufacturing planning.	• Don't under any circumstances enter a bioclean area without approval.
• Return accidentally contaminated materials to the decontamination area or, when necessary, request and apply decontamination procedures.	• Don't deviate from manufacturing planning.
	• Don't use contaminated materials.

4.6.1 PERSONNEL MONITORING

Quality assurance shall verify that all contamination control procedures for the particular operation are followed. Any breach of the special contamination control procedure shall be immediately documented on a nonconformance report and forwarded to the contamination control board for disposition.

During the assembly or test of the spacecraft in the class 100 laminar downflow clean room, quality assurance will not only verify that the proper procedures are followed in the clean room but also that the entering and exit procedures are followed. Typically, Quality Assurance would verify that upon entering the facility, all personnel cleaned their shoes in the rotating brush shoe cleaner, that the personnel sign-in and are on the list of authorized personnel. Quality Assurance would verify that all personnel walk on the track-off mats into the locker room and that all jewelry and undesirable objects are removed from the person and placed in a locker. Quality Assurance would also verify that the hands are thoroughly scrubbed and that the person entering washes and rinses his face, that he properly enters the air shower, that he dons fresh, clean smock, cap, face mask, boots, and gloves, and that clean garments do not become contaminated by touching the dirty floor, etc., while donning it.

4.6.2 PERSONNEL SELECTION

The biological contamination control problem on aerospace hardware is essentially a personnel problem. Humans are the prime biological contaminators of hardware. Human attitudes can negate carefully drawn cleanliness plans. Therefore, no bioclean vehicle is better than the workers who build it. These facts should be kept in mind when facilities are designed, procedures are devised, monitoring operations are planned, and hardware is being built. Highly motivated, conscientious, and reliable workmen should be used where biological cleanliness is required. In addition to the most rigorous procedures and controls, the enthusiastic cooperation of all personnel is required to ensure bioclean hardware.

Experience has shown that, in the long run, work in a clean room is distasteful to most people. In order to produce bioclean hardware in such a facility, an adequate supply of labor must be provided. Backup personnel, who must be available, increase the cost of production.

A special rate structure may be an effective device of maintaining a pool of available labor. A system of rotating personnel inside and outside the clean room is advisable to prevent complacency and to provide periods of work under less demanding circumstances. Under this arrangement, an individual receives two levels of remuneration. During his assignment in the bioclean area he suffers no penalty from reporting legitimate grounds for nonparticipation. On the contrary, he would face expulsion from the rotation system and loss of the opportunity to earn a higher income if contamination of the hardware were traced to his noncooperation.

He would run the risk of permanent assignment to the lower rated nonbioclean operation if he habitually misrepresented his condition of health for the sake of avoiding work in a highly controlled area.

Such a system would remove incentive or onus from true reports by a worker on the state of his health as it affects the biocleanliness of his work. This is a necessity because, otherwise, people may be tempted to hide or invent adverse conditions of health which require their exclusion from bioclean work.

The National Aeronautics and Space Administration is currently sponsoring a series of orientation courses for professional technical workers in order to familiarize them with microbiology. Similarly, industry will have to institute training programs for their workers in clean rooms and other sensitive areas to familiarize them with bioclean procedures. Many industrial clean room operators currently run such training programs, and the proposed bioclean training should be fashioned after them. See Section 1.4.3.

4.6.3 PROTECTIVE GARMENTS

4.6.3.1 Masks

Protective garments are the principal means of preventing transfer of contaminants from humans to hardware. Frequent changes of masks are recommended to prevent overloading with organisms.

4.6.3.2 Gowns

An itemized listing of the effectiveness of uniform types is shown below:

a. The conventional surgical gown or smock worn over street clothing does little or nothing significant to prevent the escape of bacteria from the body.

b. The replacement of street clothes with freshly laundered dress does not significantly reduce the dispersion of bacteria.

c. A two-piece suit divided at the waist, loose and comfortable neckline, and open-end short sleeves do not provide important sites for the escape of skin organisms.

d. The only escape of bacteria in significant numbers occurs at the ankles.

e. Tightly woven fabrics with pore radii as small as 10 microns are far more effective as filters than standard fabrics.

f. Garments rapidly lose effectiveness as filters when they become contaminated. (The change of garment with each entrance into the bioclean facility prevents saturation.)

Desirable properties of protective garments are:

a. Minimum of seams.

b. Loose-fitting to minimize abrasion against underclothing.

c. Absence of pockets, pleats, tucks, and belts.

d. Fabricated from fabrics with continuous filament yarns.

e. Tight fabric weave, such as herringbone or taffeta.

f. Minimum generation of static electricity.

g. Limited linting.

h. Sewed with nonlinting (limited linting) thread.

Guidelines for laundering clean room garments are listed below:

a. Repair all defects before washing.

b. Close zippers.

c. Launder small loads.

d. Use mild alkaline or neutral soaps or detergents.

e. Avoid bleaches if possible.

f. Use temperatures below 140°F.

g. Eliminate extraction if possible, drip dry instead.

h. Do not iron.

4.6.3.3 Footwear

NASA Standard NHB 5340.2 (Reference 4-8) stipulates that personnel shall wear lint-free nonshedding garments in the bioclean area. These garments serve as a barrier which separates the person from the hardware.

In laminar downflow rooms, any part of the body 3 inches below the spacecraft need not be covered. However, if the worker elevates himself so that his lower extremities are above the lowest point on the hardware, even the soles must be covered if adequate protection of the hardware from the biological contamination is to be achieved.

Because footwear used in a bioclean facility should remain in the decontaminated area, sneakers, tennis shoes, or some other type rubber-soled shoe are usually recommended. For covering the entire foot when a complete biological barrier is required, nylon booties provide a possible solution. The use of any of these foot coverings, however, raises a number of problems.

a. Many industrial contractors insist on the use of safety shoes in all manufacturing areas. This safety ruling would preclude the wearing of sneakers and other types of footwear preferred because of the ease of laundering.

b. Covering of the sole of the shoe can become a safety hazard on ladders and scaffolding. Booties definitely contribute to awkwardness of movement, and they increase the likelihood of tripping.

c. If special steel-toed shoes are worn without a cover for the sake of safety, sterility of footwear is difficult to achieve and maintain.

Sneakers are frequently used in clean rooms. They are easily cleaned in water at temperatures from 140 to 160°F. Twenty minutes in soap suds followed by two hot rinses and one cold rinse are often sufficient, but in many facilities wearing of sneakers is forbidden. Shoes must have a metal guard for the toes. These safety shoes are more difficult to decontaminate than sneakers.

4.6.3.4 Gloves

A major source of biological contamination of hardware results from contact with human hands; therefore, NASA Standard NHB 5340.2 (Reference 4-8) prescribes:

> "Gloves, tweezers or other mechanical barriers to prevent contact between the skin and hardware should be used while working with or handling sensitive parts to avoid contamination of those parts by loose skin, microbiota, or natural skin oils. Solvent contact with hands should be avoided, as many solvents remove natural skin oils causing excessive 'skin peeling' or flaking."

Although prevention of biological contamination is effectively achieved by the use of gloves, the following hazards encountered in their use should be considered:

a. Powdered gloves are not suitable for clean room use because they shed particulate materials.

b. Many gloves made of thin plastics, in order to retain touch sensitivity, are highly susceptible to puncture.

c. Gloves made of thick materials tend to minimize the operators touch sensitivity and make handling of small items difficult.

d. Unlined plastic and rubber gloves often cause severe sweating of the hands when worn for extended period.

e. Some plastic gloves, particularly those containing vinyl compounds, are highly plasticized. The plasticizers tend to be leached from the gloves and deposited on the hardware. When solvents are present this is a severe problem.

f. Cotton gloves tend to shed particulates.

g. Gloves made of nylon, dacron and mixtures of synthetic fibers are comparable and may be laundered and sterilized repeatedly. However, they are prone to snags and may not be as effective as rubber and/or plastic gloves as a barrier to biological contamination.

Some suggested guidelines in selecting gloves for use on a sterilization program that minimizes these hazards are:

a. Use unpowdered gloves.

b. Use Latex rubber gloves when solvents are used. An inner glove of mercerized cotton could be worn to alleviate the perspiration problem.

c. An alternate solution would be the use of lined rubber gloves which are stronger, yet retain sufficient flexibility and touch sensitivity.

The bioclean requirement adds an additional task, namely, maintenance of sterility or of a low level of biological population, to those usually demanded of packages. There is fairly general agreement on the fact that current aerospace packaging methods are inadequate to satisfy all present requirements. The additional bioclean requirement complicates the problem.

Extreme care must be taken in the preparation of packaging procedures and in the choice of packaging materials and configurations. If this is not done, the package is quite likely to destroy the level of cleanliness of the packaged item which has been laboriously achieved by previous manufacturing and decontaminating operations.

The following section contains criteria for bioclean packaging, information on packaging materials, typical packaging procedures and examples of good packages in current use.

4.7 PACKAGING

Only the problems of microbiologically clean packaging will be considered here, with examples of representative approaches from existing controlled and routine packaging. Packaging problems assume a major importance in a bioclean spacecraft program.

The purpose of packing is to protect the product from detrimental environmental factors. In the aerospace industry, reliability requirements place a premium on cleanliness. Cleanliness specifications for aerospace packing usually outlaw the use of wood, paper, box board, and the ordinary forms of dunnage. Materials which generate gross particulates are unacceptable. Where cleanliness is critical, the package itself becomes potentially a hostile environment for the hardware. Logically, the surface of the package in contact with the item it encloses must meet the same standards of cleanliness as the item itself. Examples of the required cleanliness levels applicable to package designs and materials are given below:

Location	Particle Size (microns)	Number of Particles
Vehicle Surface	>250	30/ ft^2
Pneumatic System	>100	0
Filter Element	>100	10

Clearly, those restrictions on contamination narrow the choice of appropriate materials and limit selection to the field of plastics and metals.

Following is a list of packing objectives and materials used in the aerospace industry. It shows that thin-gage metal is the most versatile material to satisfy these objectives. However, it is not necessarily the most economical and convenient material to apply. Plastic film is more readily adaptable to a variety of configurations and provides a seal that is easily established.

Objective	Material
Protection from physical forces	Rigid outer enclosure of metal or plastic
	Rigid or semi-rigid foamed plastic
	Metal or rubber shock mounts
	Crush-up structures
Protection from vapor and moisture	Heat sealable plastic film
	Hermetically sealed metal canister or enclosure
	Glass
Protection from particles	Heat sealable plastic film
	Rigid plastic container
	Metal container
	Glass

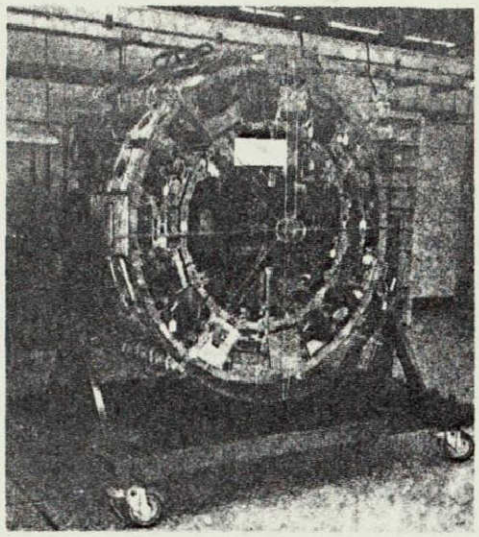
Thus, because of low cost and ease of application, plastic film is widely used packing material in the aerospace industry. Its main deficiency is its inability to shield the hardware from impact. Ordinarily, this shortcoming is overcome through the use of a rigid envelope to provide impact resistance. Table 4-8 presents plastic film selection guidelines.

Table 4-8. Suggested Guidelines for the Selection of Plastic Film Materials for Packing

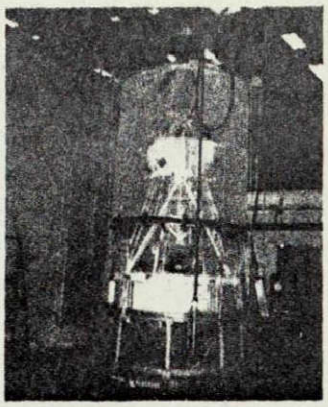
Designation	General Properties	Water Vapor Permeability (maximum) (g/100 in^2/24 hr/atm/mil	Water Absorption (maximum) (percent)	Thickness (0.001 in.)	Application	Cleanliness Level of Package	Recommended Material
Primary Barrier	• Water vaporproof • Waterproof • Greaseproof • Liquid oxygen compatible • Heat sealable	0.1	0.005	1.8 ±15%	• Precision cleaned parts • Liquid oxygen systems • Water vapor sensitive hardware	Same as material to be protected	Aclar
Primary Barrier	• Waterproof • Greaseproof • Abrasion resistant • Heat sealable	10	3	1.8 ±15%	• Precision cleaned parts where high abrasion resistance is required	Same as material to be protected	Nylon 6
Primary or Secondary Barrier	• Moderately water vaporproof • Waterproof • Heat sealable	0.5	0.05	6 ±20%	• Precision cleaned parts • Protection of primary barrier	Same as material to be protected.	Polyethylene
Secondary Barrier	• Moderately water vaporproof • Waterproof • Heat sealable	0.5	0.05	6 ±20%	• Protection of primary barrier		Polyethylene

FOLDOUT FRAME

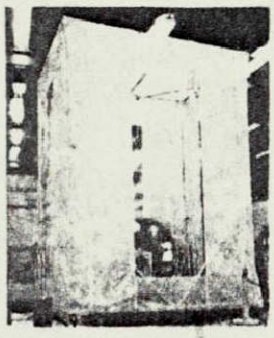
FOLDOUT FRAME



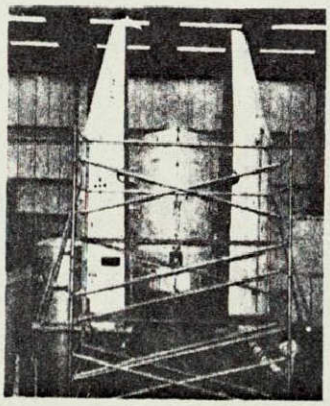
TRANSPARENT CANISTER FOR MAJOR SPACECRAFT SUBASSEMBLY



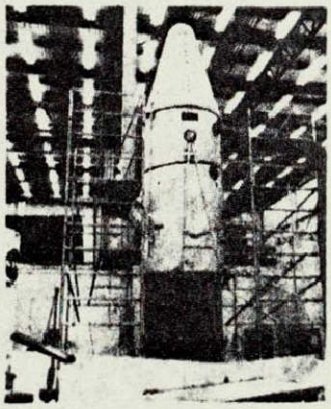
PLASTIC SHROUD FOR ASSEMBLED SPACECRAFT



SPACECRAFT ENCLOSED IN PROTECTIVE COVER



METAL CANISTER (OPEN) FOR ASSEMBLED SPACECRAFT



METAL CANISTER (CLOSED) FOR ASSEMBLED SPACECRAFT

Figure 4-5. Special Packages

The bioclean requirements associated with planetary landers necessitate the incorporation of a biological contamination barrier in the design of the package. No single material fulfills all of these requirements. Thin-gauged metal and plastic film, however, perform satisfactorily in the majority of cases when properly applied. The following list shows the most desirable features of such barriers:

- Readily sealable
- Abrasion resistant
- Puncture resistant
- Non-shedding
- Easily cleanable
- Compatible with ethylene oxide
- Permeable to ethylene oxide
- Resistant to high temperature (300° F) and moisture
- Impermeable to moisture

In a bioclean spacecraft program, packing is required not only for the completed vehicle and its components, but also for many other items as shown on the opposite page.

TYPICAL PACKING CHECKLIST

Item to be packaged	Objectives	Requirements	Package
Plastic gloves	Sterility maintenance	• Heat sealable • Permeable to ETO	• Polyethylene film bag
Dacron or nylon uniforms	Sterility maintenance	• Heat sealable • Permeable to ETO • Transparent	• Polyethylene film bag
Dacron or nylon uniforms	Sterility maintenance	• Compatible with steam	• Kraft paper
Assembled capsule	• Sterility maintenance • Protection from degradation • Transfer from assembly to launch site	• Hermetically sealable • Puncture resistant • Transportable • Resistant to impact and shock	• Metal canister • Plastic shroud
Small electronic piece parts	• Low level of biological contamination • Protection	• Compatible with organic solvents • Easily sealable • Permeable to ETO	• Plastic film bag • Petri dish with film sheeting
Electronic modules	• Low level of biological contamination • In-house handling • Protection	• Cleanable • Re-usable • Suitable for convenient shelf storage	• Plastic boxes • Polyurethane foam padding encapsulated in plastic film
Electrical harnesses	• Same as electronic modules	• Same as electronic modules	• Peg board • Plastic sheeting • Plastic tape
Pneumatic and hydraulic components	• Low level of biological contamination • Freedom from particulate contamination • Protection	• Compatible with organic solvents • Easily sealable • Permeable to ETO • Compatible with working fluids (i.e. LOX)	• Plastic film • Adhesive tape • Metal container
Hand tools	• Low level of biological contamination	• Compatible with organic solvents • Easily sealable • Permeable to ETO	• Plastic film bag • Metal container

4.8 REFERENCES

4-1 "Procedures Manual for Planetary Spacecraft to be Sterilized by Heating," Vol. II - Manufacturing Procedures, General Electric Company, Report on Contract NAS 8-11372, 1966.

4-2 "Quality Program Provisions for Space System Contractor," NASA Quality Publication NPC 200-2, April 1962.

4-3 "Space Vehicle Stage Analysis and Checkout Guidelines," NASA-MSFC Publication SR-QUAL-64-13, May 1964.

4-4 "NASA Standard Procedures for the Microbiological Examination of Space Hardware," NASA, Publication NHB 5340.1, Washington, D.C., August 1967.

4-5 "Standard Operating Procedures for the Experimental Clean Assembly and Sterilization Laboratory," Space Biology Branch, NASA Goddard Space Flight Center, Greenbelt, Maryland, July 1966.

4-6 "Development of Quality Assurance Requirements for Planetary Spacecraft to be Sterilized by Heating," General Electric Company Report 68SD4250, Contract NAS8-21139, December 1968.

4-7 Avco Corporation, "Sterilization Assembly Development Laboratory (SADL) - Quality Assurance Program Plan," Report for Jet Propulsion Laboratory - JPL Document SADL 002.01, August 1967.

4-8 "NASA Standards for Clean Rooms and Work Stations for the Microbially Controlled Environment," NASA Publication NHB 5340.2, Washington, D.C., August 1967.

4-9 "Clean Room and Work Station Requirements, Controlled Environment," Federal Standard 209a, General Services Administration, August 1966.

4-10 Portner, D.M., "Microbial Contamination Obtained on Surfaces Exposed to Room Air or Touched by the Human Hand," Protection Branch Test Report No. 1-64, Physical Defense Division, U.S. Army Chemical Corps, Fort Detrick, Maryland, July 22, 1963.

4-11 Kapell, G.F., J.J. McDade, and T.R. Gavin, "Experimental Assembly and Sterilization Laboratory (EASL) Operations: Phase I, "Jet Propulsion Laboratory TR 32-941, April 15, 1966.

SECTION 5

DECONTAMINATION AND TERMINAL STERILIZATION

SECTION 5
DECONTAMINATION AND TERMINAL STERILIZATION

5.1 INTRODUCTION

This section describes the Quality Assurance activity required during the decontamination and terminal sterilization of a spacecraft lander. The currently preferred procedure for achieving a sterile planetary lander is assembly under closely controlled environmental conditions to obtain a low biological population, followed by possible chemical decontamination, enclosure in a biological barrier, and subsequent dry heat sterilization. To avoid excessively long sterilization times which may adversely affect the reliability of critical lander systems, assembly of the lander with a low biological population before terminal sterilization is necessary. This requirement fundamentally affects Quality Assurance activity by projecting it into the area of microbiological control. The maintenance of particulate and biological cleanliness becomes as important as functional reliability. Sterility is an absolute term meaning a complete absence of life. Regardless of the definition of life, the concept of the term remains unchanged. Decontamination is the reduction in the number of living organisms, from any original condition, to a lesser number but greater than zero. Biologically, decontamination means killing or removing some of the organisms, but not all, from some item. Both decontamination and sterilization are used for the treatment of planetary spacecraft.

Decontamination also occurs when the death rate of a population exceeds the birth rate. When living space, moisture, available nutrients, and atmospheric conditions become unsuitable for the normal rate of reproduction, die-off occurs (i.e., the mortality rate exceeds the reproduction rate) and the numerical size of the population decreases. Die-off can be induced by deliberately making conditions unsuitable for growth.

Decontamination procedures are carried out throughout the assembly and checkout phase. Some decontamination results from organism due to careful handling, while some of it is due to deliberate chemical and heat decontamination treatment. Experience has shown that clean and careful handling of hardware prior to and during assembly would result in a spacecraft having less than 10^5 spores on its surfaces (Ref. 5-1).

Results obtained in the current program indicate microbial burden estimates of less than 10^6 for checkout in nonbioclean facilities, but using careful handling and protection of hardware. These microbial burden levels appear to fall within the currently specified limits required before entering terminal sterilization, in order to keep sterilization time at an acceptable minimum.

Although required decontamination levels before terminal sterilization and the required sterilization time have been specified in previous programs like Voyager, no specific NASA requirements exist at this time. However, results from numerous existing NASA-sponsored studies can provide sufficient information to permit fairly close estimates of probable requirements. References 5-4 and 5-9 provide some estimates of sterilization requirements. Reference 5-5 provides a preliminary draft of a NASA Planetary Quarantine document. Although the necessary elements required for a successful quality assurance plan on a spacecraft to be decontaminated and sterilized are available, it is incumbent upon the performing organization to obtain approval from the cognizant program planetary quarantine officer before such a plan is implemented.

Decontamination and subsequent canister mating activities for test spacecraft have been carried out by Jet Propulsion Laboratory (Ref. 4-5), General Electric (Ref. 5-3), and others. Thus, techniques and procedures for potential planning activities exist. What is needed, however, are specific quality assurance plans and procedures for a specific spacecraft, mission and, most importantly, performing organization. Selective development work to arrive at the most cost-effective procedures can then be carried out.

5.2 GENERAL GUIDELINES

The general guidelines shown here from the terminal sterilization quality assurance philosophy. Whenever detail requirements are not provided, these guidelines are to be followed to achieve or derive the detailed requirements.

a. The Quality Assurance activity should be conducted concurrently with assembly and check-out operations so that deficiencies in microbiological quality can be be discovered, corrected, and verified in a timely manner before terminal sterilization.

b. Personnel access to, and work practices in the lander-canister area should be closely controlled to maintain contamination levels within the area.

c. Status and anticipated progress of operations should be reported at regular intervals and be compatible with the data system.

d. No analysis or treatment will be performed, except by the use of a procedure approved by the procuring agency or NASA Planetary Quarantine Officer.

e. A complete and accurate log of all the significant events that occur during the decontamination and sterilization operations should be prepared.

f. The microbiological adequacy of all assembled units should be demonstrated. No vendor data will be accepted in lieu of data to be obtained during assembly and checkout operations.

5.3 GENERAL OBJECTIVES

Some of the unique objectives of the Quality Assurance function during the decontamination and terminal sterilization operations are as follows:

a. To evaluate and certify the facilities, personnel, equipment and procedures for microbiological quality during decontamination, sterilization and testing operations

b. To verify the adequacy of microbiological monitoring processes

c. To verify the functional and microbial quality of decontaminated and sterilized hardware as well as canister

d. To verify the adequacy of documentation and data bank input

e. To collect and furnish data for decontamination quality analysis

f. To collect and provide defect information so that timely corrective action can be taken

g. To verify that a biological barrier is attained after assembly of the canister to the lander

h. To verify that the integrity of the biological barrier has not been violated between terminal sterilization and spacecraft mating

5.4 GENERAL REQUIREMENTS

Quality Assurance will participate jointly with planetary quarantine personnel in the verification documentation, monitoring, and certification of planetary lander hardware during the decontamination and sterilization procedures.

While Quality Assurance personnel do not set the requirements, they are responsible for the systematic verification of conformance to prescribed specifications and documents, utilizing techniques developed for current hardware programs.

Some specific requirements for the decontamination and sterilization phase are as follows:

a. Establish and follow procedures for controlling contamination level in facilities where decontamination and sterilization is to be carried out.

b. Establish and follow procedures for collecting, storing, and analyzing assay data to estimate contamination loads.

c. Provide a system of data collection, storage and dissemination to assure that the status of component/assemblies is available.

d. Provide for monitoring critical contamination sampling events and to maintain certification of facilities, personnel and procedures.

5.4.1 GENERAL CONSTRAINTS

Quality Assurance will participate in the establishment of procedures for producing a sterile lander which meets NASA requirements. A typical procedure based on an analysis of the contamination factors, design requirements, practical manufacturing and test procedures, and qualification program is as follows:

a. Assure reliability of sterilizable components by:

- Conducting suitable qualification tests on all piece parts, materials, sub-assemblies, assemblies and systems which are candidate types for flight hardware

b. Control contamination by:

- Carefully selecting and training clean room and assembly personnel
- Designing the lander system for low burden accumulation rates and easy decontamination

c. Terminally sterilize the Lander System by:

- Determining the biological contamination load
- Applying heat as specified by NASA procedures to reduce contamination to the specified probabilistic level

d. Maintain Sterility by:

- Designing a Sterilization Canister which keeps a positive differential pressure inside at all times, from sterilization through launch
- Employing a system which requires no poststerilization adjustment
- Monitoring pressure and seal integrity continuously
- Using separation techniques which generate no debris to contaminate the planet or lander, and which will not allow contamination crossover from the unsterile spacecraft.

5.5 PLANNING AND SCHEDULING

Decontamination and terminal sterilization activities require the integration of quality assurance tasks with all other functional and operational tasks in order to achieve the highest degreee of microbiological cleanliness of the spacecraft. To accomplish this integration, extensive planning and scheduling will be required by quality assurance personnel, in the achievement of all required tasks within time, space, and budget constraints.

Quality assurance will utilize all necessary analysis tools, such as the mathematical bioburden prediction model (see Section 2.8), in order to predict potential contamination problems, before they occur. Quality assurance will schedule all inspections, biological sampling, and related activities on a minimum interference basis.

The following examples illustrate additional activities in planning which quality assurance should do.

a. Monitor all personnel procedures and activities on or near the spacecraft 24 hours a day, by visual surveillance.

b. Require lander system decontamination when the total burden of contaminants exceeds certain levels.

c. Schedule all personnel access in such a way as to minimize personnel contact with the spacecraft.

d. Coordinate room certification and spacecraft movements to avoid delays.

e. Avoid certification-caused delays.

f. Maintain a display master schedule of all in-process inspection, biological assays, and results.

g. Cooperate with engineering, assembly, planetary quarantine and test personnel to integrate the schedule.

h. Prepare contingency plans for contamination breaks or violations.

The end result of these planning activities should be the smooth and efficient flow of hardware and monitoring procedures with a minimum of overlap, confusion and subsequent contamination control violation.

5.6 TERMINAL STERILIZATION

Because terminal sterilization using heat is the only NASA-approved method at the present time, this is the only method which will be considered. Section 1.3 describes the current procedures. As conceived at present, a canister (providing a biological barrier) will be used for encapsulating the landing vehicle before, during and after terminal sterilization. Sterility of a vehicle, enclosed in a biological barrier, can be certified by inference only, since any sampling or biological assay would require violating this barrier. Thus the necessary quality assurance procedures for analyzing, measuring and certifying the adequacy of the sterilization process parameters and preparation take on added importance (Ref. 5-4).

5.6.1 STERILIZATION PLAN

For unmanned planetary missions, NASA requires that a sterilization plan be prepared. (Ref. 5-5). The sterilization plan should include the necessary quality assurance provision to provide adequate surveillance and verification of all significant activities, functional as well as planetary quarantine oriented.

Among the requirements shown in such a plan are, for example, the following:

a. A description of the procedures used to qualify the biological effectiveness of the terminal sterilization process cycle. This should include the procedures used to qualify facilities and equipment needed to produce the process cycle

b. A description of the criteria to be used to determine acceptable application of the terminal sterilization process

c. A description of the procedures to be followed in the event of accidental recontamination after initial sterilization or in the event post-sterilization repair is nesessary

d. A description of the microbiological assay, monitoring, and quality assurance procedures used in conjunction with the development, qualification, and application of the terminal sterilization process

e. A description of decontamination procedures planned to be used to reduce bacterial populations before sterilization

f. A description of the environmental conditions which bound the terminal sterilization process cycle. It is expected that these boundary conditions will be used to derive flight hardware qualification criteria. Boundary conditions to be given should include such items as:

    1. Maximum and minimum temperature

    2. Maximum and minimum rate of change of temperature

    3. Maximum and minimum humidity

    4. Ambient gas composition

5.6.2. PARTIAL CHECK LIST

The following items must, among others, also be verified by quality assurance.

a. Initial microbial population prior to canister mating for lander and canister

b. Adequacy of canister with respect to leak tightness

c. Adequacy of internal canister and spacecraft temperature instrumentation

d. Adequacy of canister/vehicle alignment

e. Adequacy of vent and fill connections for canister

f. Suitability of facility where canister and vehicle are mated

g. Conformance of terminal sterilization facility with requirements. This includes the certification of temperature measurements and recording equipment, as well as the adequacy of the heating and cooling equipment.

5.6.3 VERIFICATION OF STERILITY

According to the latest NASA procedures (Ref. 5-5), a planetary landing capsule shall be considered to have met the required probability of a finite number of organisms surviving the sterilization cycle, provided that:

a. There has been an analysis performed which demonstrates that the imposition of the terminal sterilization process cycle parameters on the capsule produces the required probability.

b. It has been demonstrated that the biological population of the capsule before terminal sterilization are within specified limits; e.g., the number, type and distribution of organisms are within the capability of the terminal sterilization process to reduce such population to predictable levels.

c. It has been verified that the specified terminal sterilization cycle parameters, such as time and temperature have been properly imposed on the capsule.

The above requirements clearly indicate a need for adequate quality assurance procedures as well as a need for a data bank to provide inputs to a mathematical prediction model (see Sections 1.5, 2.8, and 2.10)

5.7 STERILIZATION CANISTER

The canister currently serves as the biological barrier, which is used to encapsulate the vehicle. After assembly and checkout the complete landing vehicle is mated to the canister under bioclean conditions, with biological monitoring per NASA Standard NHB 5340.2.

The canister may be made of flexible plastic, metal or other material suitable for the temperature cycles approved and still able to maintain biological barrier integrity after temperature exposure.

The following canister constraints, based on Reference 5-5, are provided:

a. Biological canisters which are continuously maintained at a static pressure of at least 5 inches of H_2O above the ambient pressure shall be considered biologically sealed.

b. Biological canisters which operate essentially at ambient pressure through the use of biological filters, shall be considered biologically sealed, provided:

   1. All canister joints, seals, and the like, have been tested and found to have zero leakage as determined by instrumentation such as helium detectors.

   2. The filter media are equivalent to the High Efficiency Particulate Air Filters ("HEPA Filters") specified by MIL-F-51068A.

5.8 STERILE INSERTION

Sterile insertion is a yet unproven technique currently under development, for the insertion of otherwise sterilized fluids, substances or parts into a heat-sterilized spacecraft or repair thereof. The reason for "sterilization by other means" due to the potential degradation of the inserted items due to heat during the heat sterilization of the spacecraft. The principal problem in the development of such techniques is the verification of the maintainance of sterility of both the spacecraft and the inserted item. This need for verification introduces a quality assurance requirement which must be defined.

These different types of insertable items introduce different techniques:

a. Liquids, Gases - The use of filtration techniques has been shown to have promise (Reference 5-6).

b. Small Solids - The split seam technique currently under development shows promise (Reference 5-7).

c. Large Systems - The Assembly Sterilizer System currently in development represents a most promising system (Reference 5-8).

Although these techniques appear to present desirable methods, it should be noted that none of them at present are better than just marginal. They are not to be used in a NASA-approved planetary quarantine program without prior NASA Planetary Quarantine Officer approval.

5.9 DECONTAMINATION

As stated in the beginning of Section 5.1, decontamination is defined as the reduction of the microbial population. Such a treatment may be desirable in two cases:

a. Reduction of microbial population before terminal sterilization

b. Reduction of microbial population as an end result, where sterilization is not required.

These are discussed as follows:

5.9.1 DECONTAMINATION OF PARTS, COMPONENTS AND SUBSYSTEMS

To generally reduce the severity of the terminal sterilization process, it may be desirable to decontaiminate either all of, or certain elements of hardware before its incorporation into a planetary capsule. Decontamination of such hardware (while at a level of assembly lower than that of a complete capsule) may be accomplished by any suitable method provided that:

a. An identification is made in the Sterilization Plan of all items of hardware which are planned to be decontaminated before incorporation into the capsule. Methods of qualifying decontamination techniques or process cycles are given in the Sterilization Plan.

b. Each decontamination technique or process cycle planned to be used in decribed in a decontamination process specification, which includes a description of the applicable qualification procedures and quality assurance requirements.

c. The detail specification covering each item of hardware to be decontaminated lists, as an applicable document, the decontamination process specification which is planned to be used.

d. The decontamination techniques or process cycles employed do not degrade the ability of the complete capsule to withstand the terminal sterilization "dry heat" process cycle.

Although this manual is concerned primarily with sterilization and the attendant decontamination cycles, it is recognized that, depending on the planet of interest and the planned mission, terminal decontamination only of a planetary capsule (i.e., without terminal sterilization) may be sufficient to satisfy the probability of planetary contamination.

For such cases, terminal decontamination of the planetary capsule shall be accomplished by exposing the planetary capsule to either a modified "dry heat" environment or to an ethylene oxide environment or the other chemical decontaminant treatment. Such treatments are described in detail in Referenc 5-9, Biological Handbook for Engineers.

5.10 REFERENCES

5-1 Christensen, M.R., Green, R.H. and Stern, J.A., "Microbial Sampling Program for Mariner Venus 67 Flight Spacecraft (Mariner V)" JPL Space Program Summary 37-46 Vol. IV, pp.48-55, Pasadena, (1967).

5-2 "Development of Quality Assurance Requirements for Planetary Spacecraft to be Sterilized by Heating," General Electric Company Report 68SD4250, Contract NAS8-21139, December 1968.

5-3 Design Criteria for Typical Mars Landing Capsules Requiring Sterilization, NAS 8-11372-Phase III-General Electric Co. Documents 67SD4223, 1967.

5-4 Craven, C., Stern, J.A., and Ervin, G.F., "Planetary Quarantine and Space Vehicle Sterilization Astronautics & Aeronautics, August, 1968.

5-5 "Planetary Quarantine Provisions for Unmanned Planetary Missions" NASA Publication NPQ 100-1 October, 1968 Edition.

5-6 Ernst, R.R., Evaluation of Filters to Sterilize Liquids and Gases, Report, Wilmot-Castle Co., Rochester, New York, 1967.

5-7 Rothstein, A.A., et al., Develop and Test of a Sterile Insertion Repair Technique Contract NAS8-21122, Final Report, Martin-Marietta Corp, Denver, Colorado, January, 1968.

5-8 Crawford, J.G., and Zanks, J.F., "The Assembly/Sterilizer-A facility for the Sterilization and Assembly of Spacecraft" in Stepping Stones to Mars, AIAA/AAS Conference, Baltimore, Maryland, March 1966.

5-9 Biological Handbook for Engineers, NASA CR-61237, (General Electric Co.), George C. Marshall Space Flight Center, Huntsville, Alabama, June 1968

SECTION 6
MICROBIOLOGICAL PROCEDURES CONTROL

SECTION 6
MICROBIOLOGICAL PROCEDURES CONTROL

6.1 INTRODUCTION

This section describes pertinent aspects of the microbiological procedures required as part of the Quality Assurance function in producing a heat sterilized planetary spacecraft. Microbiological assays will be the basic monitoring tool in all phases of these Quality Assurance procedures. All activities necessary in conducting such assays shall be monitored to assure quality certification for procedures, equipment and personnel.

6.2 SCOPE

The scope of this section encompasses a plan for the verification of microbiological quality of a spacecraft, spacecraft part, component or assembly from receiving inspection through the terminal sterilization process. This plan covers standard microbiological sampling procedures, facilities and equipment, microbial sampling plans, certification of materials and equipment, receiving inspection, data and reports.

This plan is designed to assure the adequate collection of microbiological data with the verification of quality and conformance being performed by Quality Assurance surveillance. Such surveillance must include monitoring (1) all sampling of all laboratory materials; (2) the personnel dressing procedure for entering a controlled environment facility; (3) all decontamination processes especially as concerned with assembly tools and subassembly units; (4) all assembly operations including; operation of the facility, microbiological assays, all laboratory operations and techniques, recording of all activity, reporting of all abnormal activity; and establish requirements for statistical bases of microbiological sampling to include coupon allotment, swab samples, and hardware items.

6.3 GENERAL GUIDELINES

The following guidelines establish an approach which integrates microbiological sampling with quality assurance engineering, monitoring, and checkout procedures for spacecraft hardware.

The flow of events shall follow a logical, well-planned sequence that permits adequate microbiological sampling at each established testing point for raw material, component, subsystem, system or vehicle with a minimum of duplication and with the most efficient use of time, manpower, equipment and facilities.

Microbiological sampling operations will be integrated with the engineering and check-out plan to utilize the available time and facilities most efficiently. All sampling will be accomplished in a logical sequence and the results recorded in a format designed for future analysis and data bank storage.

The organization responsible for the microbiological sampling and for assuring the microbiological quality of the hardware will use trained, skilled personnel who thoroughly understand the goal of such a program. A sterility control group including representatives from several functions will establish the sampling criteria from the design specifications and design objectives. They will be responsible for interfacing with the NASA Planetary Quarantine Officer for the acceptance or rejection of test results.

Microbiological sampling operations will not be performed without procedures which have been submitted to and approved by the cognizant Microbiologist, Quality Assurance, Engineering, Program Management, and the NASA Planetary Quarantine Officer. Such procedures shall provide for the following controls:

a. Statistically reliable samples of each component will be evaluated before and after each functional testing. Integrity of all vendor packaging material will be checked before usage.

b. Vendor data will not be accepted in lieu of testing, except for expendable items or those which are impractical to test. "Spot checks" will be made on all expendable items.

c. No component or part will be accepted for microbiological evaluation without the necessary documentation or certification.

d. All component packaging, when returned for further quality testing, will have the same integrity as when delivered for microbiological testing. Any irregularities in conditions or components will be noted on travelers and passed on to the cognizant individuals.

e. Testing of components and materials will be done according to procedures that will not alter the reliability of the item or component used for further testing.

f. Components from bonded storage which show evidence of compromised packaging integrity, must be retested or reprocessed before acceptance or discarded.

g. Travelers will accompany all components tested and appropriate certification by testing individual. Test personnel will be identified by an inspection stamp or suitable identification.

h. Sufficient "lead time" will be scheduled to ensure that microbiological test results will be available before the component is used in subsequent processes.

i. A complete and accurate history will be retained on individual components by Quality Assurance as a reference for future use.

6.4 PLANNING AND SCHEDULING MICROBIOLOGICAL ASSAYS

Provision of a schedule is necessary in the microbiological sampling plan. This requirement will integrate the microbial assays with the engineering schedule. The preparation of such a plan must reflect the microbiological requirement to incubate all samples for a minimum of 72 hours with counts to be made at 24, 48, and 72 hours. Microbiological data will not be considered final until after the 72 hour counts have been evaluated.

The scheduling of microbiological assays is also an important factor in the cost of a program. Samples taken on Wednesday, Thursday or Friday will involve overtime because weekend work will be required.

The scheduling of critical microbiological assays should also be programmed into the manufacturing plan so that the incubation period does not impede manufacturing operations. A critical assay would be defined as one in which the results must be known before the next assembly step takes place.

Microbiological assays must also be planned so that the laboratory operation does not exceed its sample capacity due to facility limitations.

6.5 GENERAL OBJECTIVES

The objectives of this plan are to provide guidelines and procedures to assure the microbiological quality of all components, subsystems, systems and vehicles which will be terminally sterilized by heating. Adequate surveillance and documentation will be carried out on all operations to:

a. Assure the sterility and/or enumerate the biological contamination level of specific test items

b. Establish microbiological background levels in the assembly and testing facilities

c. Monitor the handling of hardware and microbiological samples

d. Verify the conformance to all operational and testing specifications

e. Furnish useful data in the assessment of the microbiological burden on all hardware

f. Improve the overall program quality in the prevention or reduction of the microbial contamination of the system

g. Meet NASA sterilization requirements for planetary spacecraft to be sterilized by heating

6.6 GENERAL REQUIREMENTS

The following sections establish the general requirements which are necessary to assure the adequacy of the microbiological quality of spacecraft hardware which is to be sterilized. They will assure:

a. Necessary monitoring of hardware by microbiological assay

b. Necessary Q/A monitoring of the microbiological assays

c. The assays which are performed are adequate

d. All operations are carried out according to standard operating procedures

e. Check lists are filled out

f. Proper documentation is maintained

g. The data collected is appropriate for analysis

h. Verification that the data will be analyzed to validate that the hardware meets the microbial contamination level specifications

i. That the hardware was handled in an approved fashion

j. That adequate numbers of samples have been taken

k. Adequate vendor certification

l. Additional guidelines for planning, analysis and checkout of a planetary spacecraft to be sterilized by heating

6.7 MICROBIOLOGICAL CONTROL PROCEDURES

6.7.1 GENERAL

Standard Operating Procedures (SOP's) will be prepared by the microbiologist for all microbiological assays and related activities. No testing will be attempted without the use of an approved procedure. The approval should be signed off by Microbiology, Quality Assurance, Program Management and the Planetary Quarantine Officer as well as the necessary Manufacturing groups.

The SOP provides the opportunity to examine the operation carefully in order to assure that the requirements have been reflected in the procedure and that the implementation of the procedure will result in the attainment of the objectives. Contamination problems and human error may be eliminated in advance by the careful and thoughtful preparation of procedures (SOP's). Standard procedures also establish a uniformity in the data.

6.7.2 TITLE PAGE

The procedure title page will contain the following:

a. Title of the procedure

b. Identification of item being assayed

c. Procedure number

d. Originating organization identification/operating organization

e. Revision or addenda acknowledgements

f. Approval signatures

1. Microbiologist

2. Manufacturing

3. Quality assurance

4. NASA Planetary Quarantine Officer or representative

6.7.3 TABLE OF CONTENTS

The Table of Contents should direct the reader to the major subdivisions and topics which are included in the procedure.

6.7.4 INTRODUCTION

The Introduction should contain essential information that will acquaint the reader with the general content and the scope of the operation. The Introduction provides a place for providing the reader with information on unique features of the operation, specific limitations to be observed, and sequential information relative to the microbiological assay.

6.7.5 APPLICABLE DOCUMENTS

This section should reference drawings of the items to be assayed, applicable standards, specifications and other related procedures or documentation.

6.7.6 OBJECTIVES

The objectives cite the reason for performing the operation on assays. They should be stated clearly and concisely so that their attainment is accurately assessed.

6.7.7 EQUIPMENT AND MATERIALS

All necessary equipment and materials needed to perform the microbiological assay should be listed. Standard as well as special equipment should be listed with model numbers, etc.

6.7.8 SCHEMATICS OR MATERIAL COMPOSITION/CHARACTERISTICS INFORMATION

A schematic or drawing as well as the chemical composition of the hardware to be microbiologically assayed should be incorporated if it adds significantly to the microbiologist's understanding of the potential assay problems and/or facilities Quality Assurance inspection.

6.7.9 FLOW CHARTS

A set of flow charts should be prepared which acts as a descriptor for the sequence of events in the microbiological assay process.

6.7.10 OPERATIONS

A detailed step-by-step list of the actions to be performed in their proper sequence will be tabulated in the procedure. These actions should be described to the most detailed degree.

6.7.11 DOCUMENTATION

A checklist will be written to accompany the operations procedure. This will be used by Quality Assurance to verify that the specified operations were performed, performed in the proper sequence, and according to the SOP with notations about any problems or deviations encountered in practice.

6.7.12 DATA RECORDING

Standard data sheets will be included with each procedure to illustrate the format that will by used. The data should include such items as identifying code, data, sampling technique, sample duration, sterility controls, verification of supplementary procedures and treatment, time incubation condition and time, culture medium, culture or incubation condition controls, and any other pertinent information.

6.7.13 UNSCHEDULED EVENT REPORT

An unscheduled event report detailing the event will be filed by Quality Assurance Surveillance with the microbiologist, manufacturing engineering, and Planetary Quarantine Officer. The sterility control group will act on the consequences of the event.

6.7.14 CORRECTIVE ACTION REPORT

The corrective actions that are required in response to certain nonconformance situations or malfunctions should be included as part of the procedure.

6.8 MICROBIOLOGICAL ASSAY TEAM/ FACILITIES AND EQUIPMENT

6.8.1 ASSAY TEAM

The microbiological assay team should consist of a minimum of five people. This includes two trained microbiologists, two preparation technicians, and a Quality Assurance inspector. The two microbiologists will perform assays, sample culturing, plate counting and data reporting. The preparation technicians will be responsible for preparing all media and sterile supplies as well as discrading cultures and washing glassware. The Quality Assurance inspector will monitor all critical microbiological operations and will maintain necessary documentation on such operations.

6.8.2 FACILITY

The facility will consist of a specialized laboratory for sampling a spacecraft being manufactured under controlled environmental conditions. Its general location should be adjacent to the manufacturing facility with controlled direct access ports.

The size of the facility will be mainly dependent upon the size of the microbiological assay team.

6.8.2.1 Floor Space

The floor space should include at least 250 square feet of working space per individual.

6.8.2.2 Work Bench Area

The work bench surface should be not less than 35 square feet per working individual with about 20 percent of the area utilized for support equipment.

6.8.2.3 Storage Cabinets

Storage cabinets and drawer space should be provided and should be at least 100 cubic feet per person.

6.8.2.4 Electrical Connections

Sufficient electrical outlets must be placed throughout the laboratory. At least six outlets per individual should be supplied. Both 110 and 220 voltage supplies must be available.

6.8.2.5 Heating Gas

It is recommended that gas be supplied to the laboratory for use with bunsen burners (if safety regulations allow a central gas supply). Sufficient gas jets should be placed conveniently over the work bench areas. Portable laboratory tanks may be used in lieu of a centralized source.

6.8.2.6 Lighting

Adequate overhead lighting must be supplied to the laboratory.

6.8.2.7 Preparation Area

A preparation area must be included either in the laboratory or adjacent to it. At least two double sink areas must be supplied. Hot and cold running water must be supplied to each sink. Additional cold water faucets must be attached to each sink. Adequate drain facilities must be constructed for all waste water.

The preparation area should have a distilled water supply. It is recommended that the necessary plumbing be installed to supply a running distilled water service. The source may either be a centralized still or bottled water supply.

A stove or series of hot plates should be included in the preparation area for melting and preparing culture media.

A laboratory dishwasher should be included in the preparation area. It should be of sufficient size to easily handle all of the glassware used in a day's experiment. It should have the capability of a hot detergent wash, hot and cold water rinse and a distilled water rinse.

Sterilizers should be included in the preparation area. Live steam will have to be supplied for the autoclave as well as a drain. An ethylene oxide sterilizer and a dry heat sterilizer should be included.

A low temperature ($\simeq 100^{o}C$) dry heat oven should be supplied for drying glassware.

6.8.2.8 Laboratory Carts

At least one standard three-shelf laboratory cart should be supplied for each working member of the team.

6.8.2.9 Refrigerator

At least one standard household refrigerator ($\simeq$ 12 cubic feet) should be supplied for each working member of the team. One of these refrigerators should be equipped with explosion-proof controls.

6.8.2.10 Telephones

Telephone facilities will have to be available in the laboratory for both internal and external usage.

6.8.2.11 Desk Side Computer System

A desk side computer system should be available in the laboratory area for feeding the assay data into the storage or analysis system.

6.8.2.12 Pressurized Nitrogen

A pressurized filtered nitrogen gas supply will be required. A bottled gas system may be adequate.

6.8.2.13 Exhaust Hood

An explosion-proof exhaust or chemical fume hood will have to be supplied.

6.8.2.14 Clean Bench Work Areas

Class 100 horizontal laminar flow clean benches will have to be supplied in the laboratory. At least three benches approximately 4 feet long will be required.

6.8.3 MICROBIOLOGY LABORATORY EQUIPMENT AND SUPPLIES

6.8.3.1 Basic Laboratory Equipment

Certain equipment items which must be included in a basic microbiological assay laboratory. Actual items needed may vary slightly depending on the emphasis of the microbiological sampling program. A list of the basic items needed for a minimal microbiological assay team appears in Table 6-1.

6.8.3.2 Basic Laboratory Supplies

The laboratory supplies which will be needed will depend mainly upon the size of the microbiological assay team and the number of assays being performed. An abbreviated list of specific items which will be consumed in routine microbiological assays appears in Table 6-2.

The approximate cost for basic expendable supplies for the above mentioned microbiological assay laboratory will be roughly $1,000/month. This, of course, depends on the number and type of assays being performed.

Table 6-1. Microbiology Laboratory Material and Equipment

Item	Approximate Cost	Approximate Size or Capacity	Approximate Quantities Needed for A Minimal Capacity Laboratory
Anaerobic Jars	$48.50	10 petri dishes (100 x 15 mm)	50
Accessories			
(1) Catalyst	$ 1.25	1/Anaerobic Jar	50
(2) Gas Pack	$36.00/100	1/Anaerobic Jar	1000
(3) Indicators	$ 2.00/10	1/Anaerobic Jar	100
Andersen Air Sampler (0604 Viable Particles)	$240.00		5
Accessories			
(1) Flow Meter	$10.00	0.2 to 3.0 1/m	5
(2) Gaskets	$ 1.50/doz		3
(3) Petri Dishes	$96.50/gross		Gross
(4) Timer	$10.50		5
Autoclave	$5,000	20 x 20 x 36 in.	1
Accessories			
(1) Indicators	$1.50/doz		1000
Automatic Pipetting Machine	$250.00	Up to 50 ml/stroke	1
Blender Mill	$220.00		1
Accessories			
(1) Balls	$2.00/lb		
Cavitation Meter	$150.00		1
Laminar Flow Clean Bench	$828.00	2 ft x 4 ft x 28 1/2 in Work Area	3
Colony Counter	$350.00		2
Conductivity Meter	$133.50		1

Table 6-1. Microbiology Laboratory Material and Equipment (Cont)

Item	Approximate Cost	Approximate Size or Capacity	Approximate Quantities Needed for A Minimal Capacity Laboratory
Dry Glove Box (Bacteriological)	$895.00		2
Accessories			
(1) Gloves	$42.00/Pair		10
(2) Interchange Box	$155.00		2
Dry Heat Sterilizer	$920.00	25 x 20 x 20 in.	1
Ethylene Oxide Sterilizer	$5,000.00	20 x 20 x 36 in.	1
Ethylene Oxide Sterilizing Mixture	$20.00	125 lb	
Flow Meters	$28.00	0.3 to 2.0 CFM	10
Gas Chromatograph	$2,300.00		1
Glassware			
125 ml Flask	$25.00/18	125 ml capacity	
6 liter Flask	$ 5.12	6 liter capacity	
500 ml Screw Cap Flask	$ 2.29	500 ml capacity	
4 oz Bussy Bottle	$25.00/48	4 oz capacity	
100 ml Graduated Cylinder	$ 3.00	100 ml capacity	
25 ml Pipette (Volumetric)	$32.00/18	25 ml capacity	
Hot Plate/Stirrer	$84.50	7 x 7 in.	6
Humidity Sensor	$105.00		1
Incubator	$475.00	10 ft^3	6
Isolator Flexible	$200.00	24 ft^3	3
Isolator Rigid	$1,200.00	30 ft^3	1

Table 6-1. Microbiology Laboratory Material and Equipment (Cont)

Item	Approximate Cost	Approximate Size or Capacity	Approximate Quantities Needed for A Minimal Capacity Laboratory
Leak Tester	$120.00		1
Limited Orifice	$18.00		1
Manometer	$39.00		3
Particle Counters	$6,800.00		1
pH Meter	$360.00		2
Pipette Canister	$13.50/6	6 1/2 in. dia. x 18 in.	24
Pipette Washer/Rinser	$28.50		1
Recorder	$700.00	Millivolt	2
Reyniers Sampler	$135.00		10
Accessories			
(1) Gasket	$5.00/doz		60
(2) Timer	$60.00		10
(3) Petri Dishes	$80.00/gross	150 mm x 20 mm	200
Temperature Recorders	$52.00		6
Thermometers	$3.00		12
Ultrasonic Bath	$495.00	8 x 12 x 10 in.	3
Velometer			1
Water Bath	$495.00	9 x 18 x 36 in.	6
Seriological Bath	$124.50	14 x 10 x 7 in.	2

The approximate cost to equip such a laboratory is $43,000.

Table 6-2. Required Laboratory Supplies

Item	Approximate Cost	Approximate Size or Capacity
Culture Media		
Trypticase Soy Agar	$ 10.00 ea.	1 lb
Peptone	$ 5.00 ea.	1 lb
10 ml Disposable Pipettes	$ 72.50/5.00	10 ml capacity
1 ml Disposable Pipettes	$ 77.30/10.00	1 ml capacity
Petri Dishes (Disposable)	$ 21.50/5.00	15 x 100 mm
Rodac Plates (Disposable)	$ 40.00/5.00	

The approximate cost for basic expendable supplies for the above mentioned microbiological assay laboratory will be roughly $ 1,000/month. This, of course, depends on the number and type of assays being performed.

6.9 MICROBIOLOGICAL SAMPLING PLAN

A microbiological sampling plan will be established for each item or area sampled. The sampling plan will detail the sampling technique used, the numbers of samples, the frequency or sampling interval, as well as defining the types of microorganism for which assaying is conducted.

6.9.1 SAMPLING TECHNIQUES

Defining the specific sampling technique used is important so that reliable evaluations of the efficiency and reproducibility may be determined. It is expected that the sampling techniques used on a sterilization program will be specified by the NASA Centracting agency.

6.9.1.1 Sampling Techniques for Hardware

Two basic procedures are used to sample hardware. The most commonly used is external surface sampling. This procedure is nondestructive and may be used on all types of hardware items, subsystems, systems and vehicles. Commonly used methods for external surfaces sampling are surface rinse, scrubbing with a cotton swab, a direct agar surface

contact plate, or the attachment of stainless steel strips on hardware. In an actual sampling program the methods will be specified in accordance with various hardware configurations. Small items such as individual components may be assayed using the surface rinse procedure. Items such as subsystems and larger will probably be assayed using either swabs or direct contact plates. The swabs can be used on almost any surface configuration, but direct contact plates may only be used on smooth flat surfaces. Stainless steel strips are difficult to attach and may be dangerous to the hardware if they are dropped or lost. They probably will not be recommended for flight hardware.

Figures 6-1, 6-2, and 6-3 present the flow charts for three of the sampling methods previously outlined.

The second procedure used for sampling hardware involves an analysis of the internal microbial burden. This is a destructive test, and would not be used on flight hardware, but rather used as a means of collecting background data for the "math model." Commonly used methods for determing the internal microorganisms are blending, grinding in a ball mill, shearing, fracturing or dissolution in an appropriate solvent.

Table 6-3 summarizes the efficiencies of the various methods used to sample hardware.

6.9.1.2 Sampling Techniques for Intramural Environments

The intramural environment is that environment in which the spacecraft or its hardware is enclosed. The microbiological contribution to this environment is primarily due to the circulating air in the enclosure, the personnel, materials, and supplies transferred into the enclosure. Measurements of the microbial contamination levels of the intramural environment are of a secondary data level. It is the quality of the hardware which is the concern of this program, but information gathered from the intramural environment will indicate the quality levels of microbial contaminants to be expected on the hardware.

6.9.1.2.1 Measurement of the Microbial Conatmination Levels of Intramural Air

The air of an intramural environment may be sampled for either a total particulate level or variable particulate level using volumetric sampling divices. Microorganisms may be separated from total particles by collecting the samples on nutrient culture incubating, and counting the resultant microbial colonies.

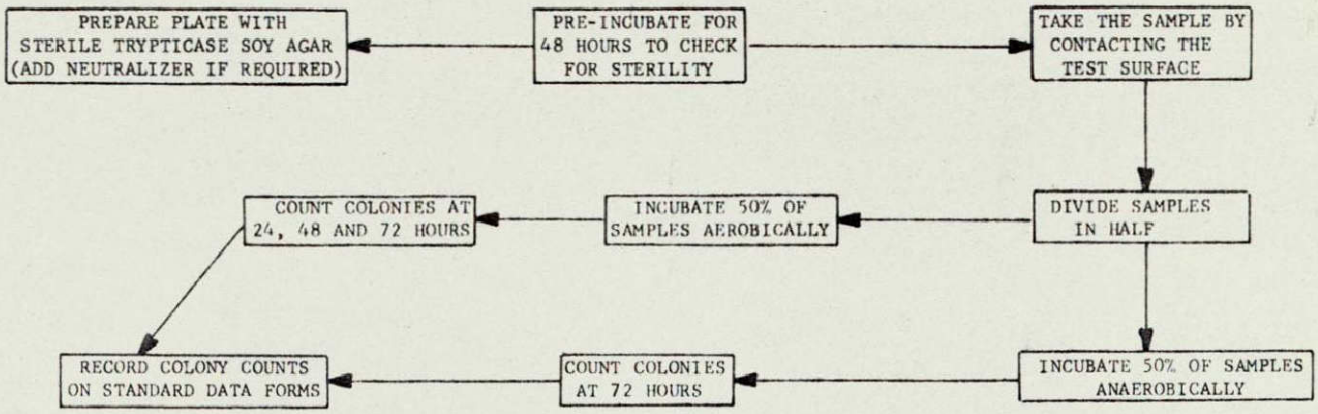


Figure 6-1. Flow Chart for Swab Microbiological Assay

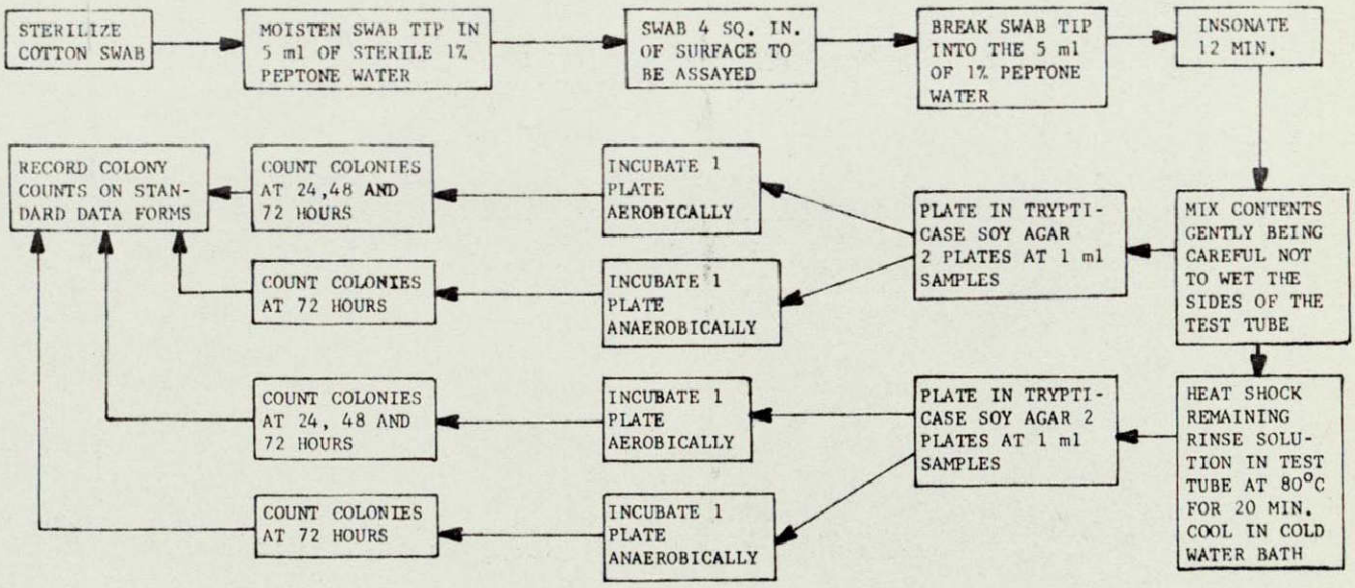


Figure 6-2. Flow Chart for Direct Agar Contact Plate

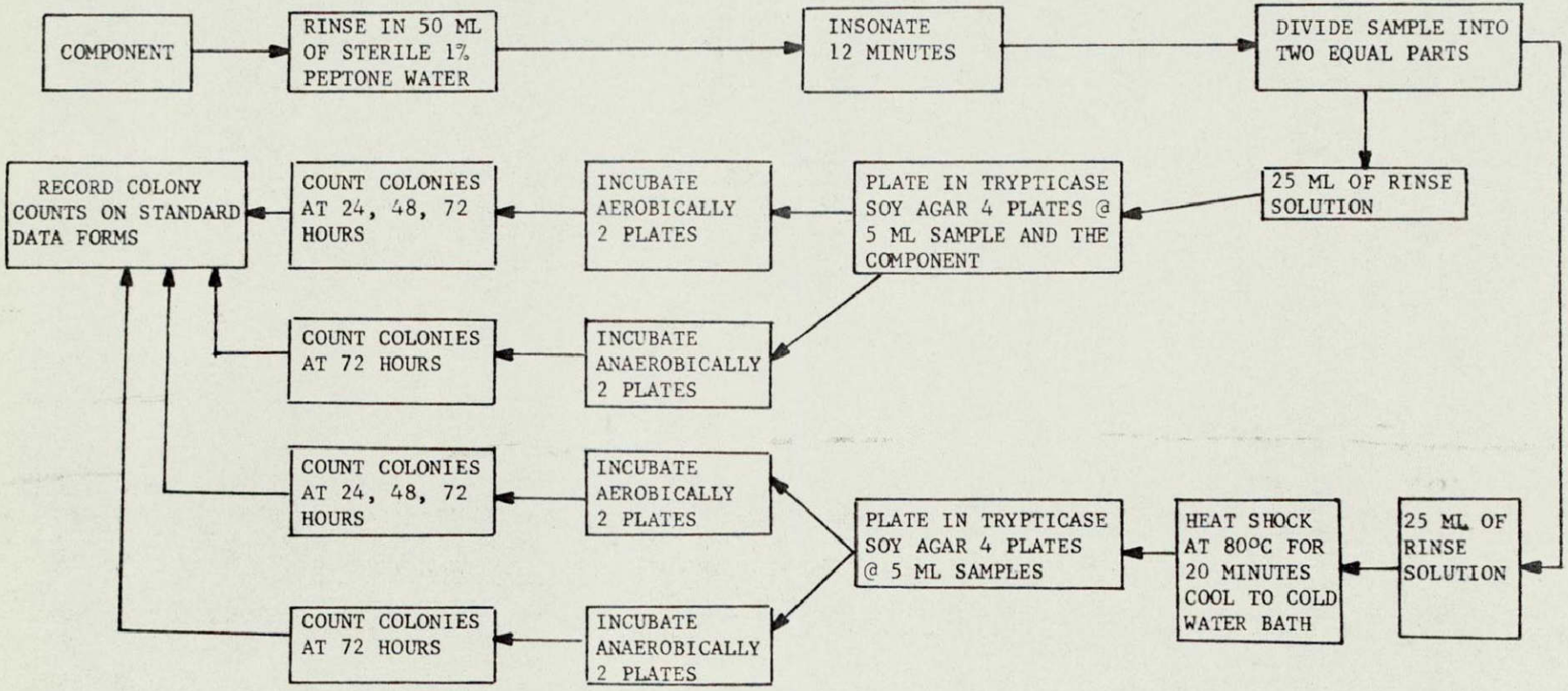


Figure 6-3. Flow Chart for Component Microbiological Assay on Stainless Steel Test Strip

Table 6-3. Summary of Reports on the Efficiency of Microbial Sampling Techniques with Comments on Known Limitations

Technique	Type Material	Reported Efficiency (Recoveries %)	Reference
Surface Sampling			
Swab	Various Surfaces	40 - 100	Angelotti et al, (1958, 1964) Bond et al, (1963)
Rodac Plate	Various Surfaces	40 - 50	Angelotti et al, (1958, 1964) Bond et al, (1963)
Rinse			
Direct Flush	Various Surfaces	80	Buchbinder et al, (1947)
Direct/ Filtration/ Culture	Varied	90 - 100	Millipore (1965)
Mechanical Agitation	Stainless Steel	50 - 100	GE (1967) (Unpublished Data)
Ultrasonic Agitation	Stainless Steel	95 - 100	Puleo et al, (1967)
Internal Sampling			
Pulverization (Ball Mill)	Silicone Rubber	7% (with 10^5 - 10^6 spores/gm inoculum)	Green et al, (1967)
	Plaster of Paris		
	Dental Inlay Materials	70 - 95	Puleo et al, (1966) Favero (1966-67)
	Paraplast		
	Epoxy	40 - 80	Green et al, (1967)

Table 6-3. Summary of Reports on the Efficiency of Microbial Sampling Techniques with Comments on Known Limitations (Cont)

Technique	Type Material	Reported Efficiencies (Recoveries %)	Reference
Blending	Balsa Wood	~100	Angelotti & Lewis (1966)
Dissolution (Solvents)	Lucite (in Acetone)	74	Green et al, (1967)
	Lucite (in Acetone)	~100	Puleo et al, (1966) Favero (1966, 1967)
	Lucite (in Acetone)	40 - 100	Angelotti & Lewis (1966)

There are several types of conventional volumetric air samples. The most commonly used sample is a slit sampler. These samplers consist of a clock, a rotating table and petri dish, a vacuum source adjusted to draw 1 CFM of air through the slit and over the petri dish. Particles in the air are impinged on the culture media long term slit samplers usually sample for 1 hour. The short term slit samplers usually sample for 15 minutes. Figure 6-4 presents the flow chart for Long Term Slit Air Sampler.

The cascade-sieve sampler characterizes the airborne viable particles into discrete sizes. This sampler consists of a series of perforated discs which are placed over culture dishes and stacked in decreasing order of pore size. The smallest pores are on the bottom. A vacuum pump draws a standard 1 CFM through the sampler. As the air cascades through the perforated discs or sieves, its velocity increases because of the reduced pore size. Particle velocity in the air stream also increases when particle velocity becomes too great to negotiate the turns designed into the cascade; they impact on the culture media. The incubation of the series of plates allows an analysis to be performed on the particles to determine which size particles were carrying the microorganisms. Figure 6-5 presents the flow chart for the Cascade-sieve Air Sampler.

A third type intramural environmental sampling technique involves the use of standardized test surfaces. These test surfaces are usually 1 x 2 inches stainless steel strips which are

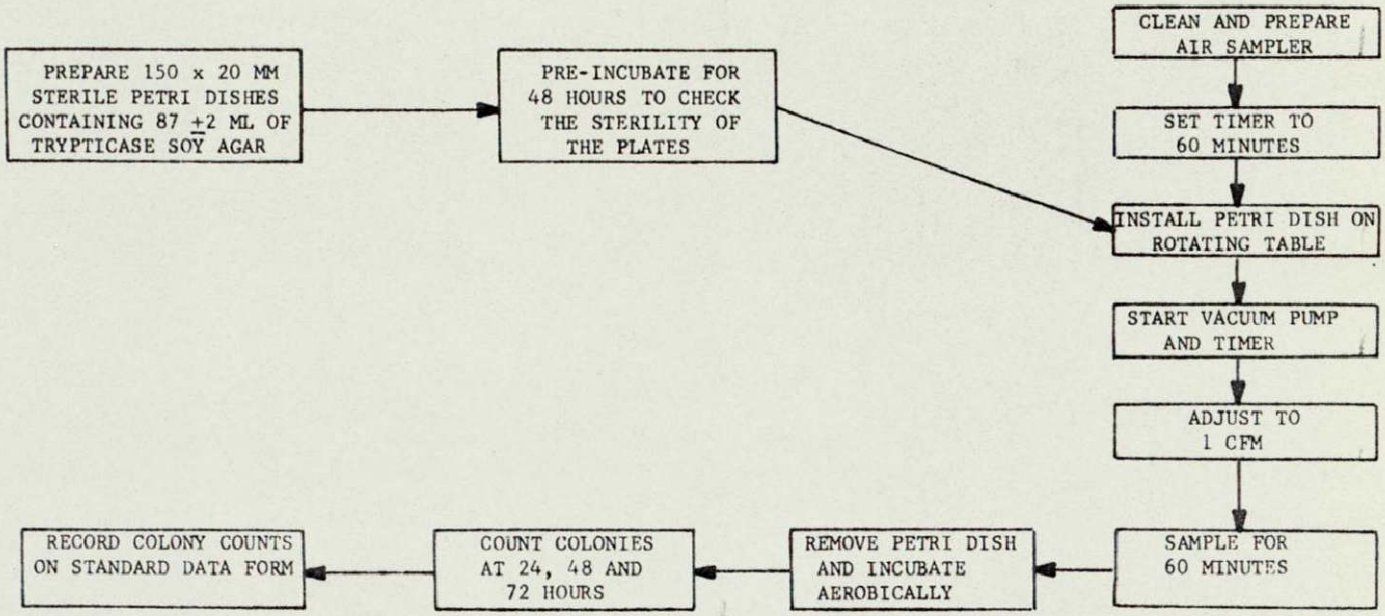


Figure 6-4. Flow Chart for Long Term Slit Air Sampler

placed on trays and exposed to the environment. These strips are assumed to be equivalent to hardware exposed the same environment in regards to their contamination or microbial quality level. However, these strips are usually oriented and tested only as horizontal surfaces facing upward. A typical hardware item would have surfaces facing in all directions. These test strips attempt to generalize what effect the intramural environment is having on the actual hardware and are much easier to control and handle then the hardware.

6.9.2 NUMBER OF SAMPLES

The actual number of samples will depend entirely upon the items or environment being sampled. Small items such as components should be totally sampled. Subsystems such as black boxes should be assayed at each sample interval to equal approximately 10 to 20 of the total surface area or percent to yield sufficient samples which can be statistically analyzed with a high degree of confidence and reliability. For a hardware item larger than subsystems, it is important to take enough samples for reliable statistical analysis.

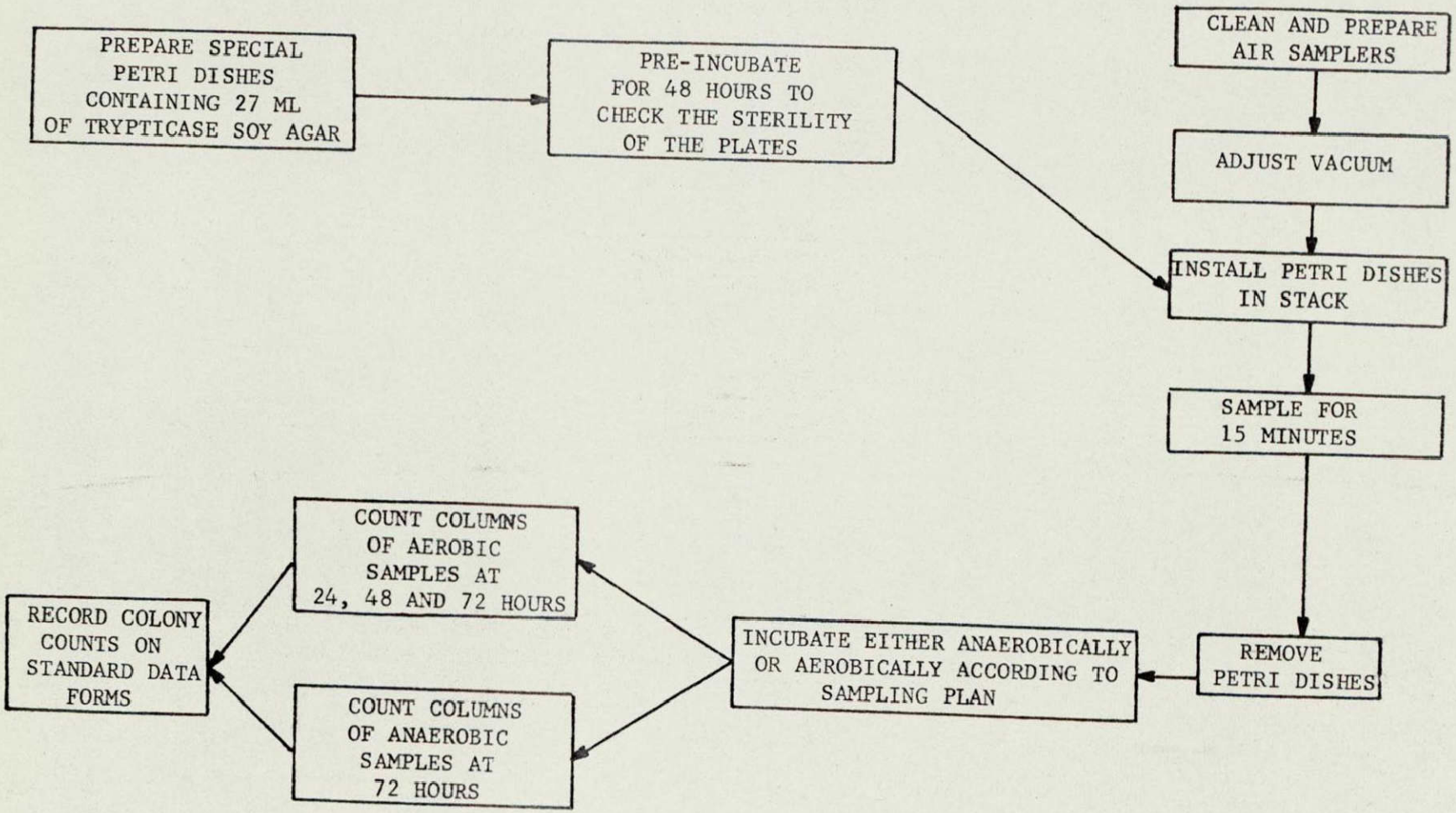


Figure 6-5. Flow Chart Cascade - Sieve Air Samplers

Samples taken of the intramural environment should also be in sufficient quantities to yield reliable statistical evaluations. At least two types of samples should be run on each environment. It is suggested that at least one of these should be an air sampling device for viable particulates. Figure 6-6 illustrates the orientation of air samplers to be used around a vehicle while it is being assembled.

6.9.3 SAMPLING FREQUENCY

The frequency of sampling will depend entirely upon the activity to which the hardware or environment is exposed. Following each period of activity the item will be assayed whether it is an assembly process, a test or storage period. The environment will be sampled on a continuous basis using settling strips. Air samples will be run at any time work is being performed on the hardware.

6.9.4 TYPES OF MICROORGANISMS TO BE ASSAYED

The types of microorganisms to be assayed for include aerobic forms, anaerobic forms, vegative cells, spores, bacteria and fungi. The specific forms will be indicated by the

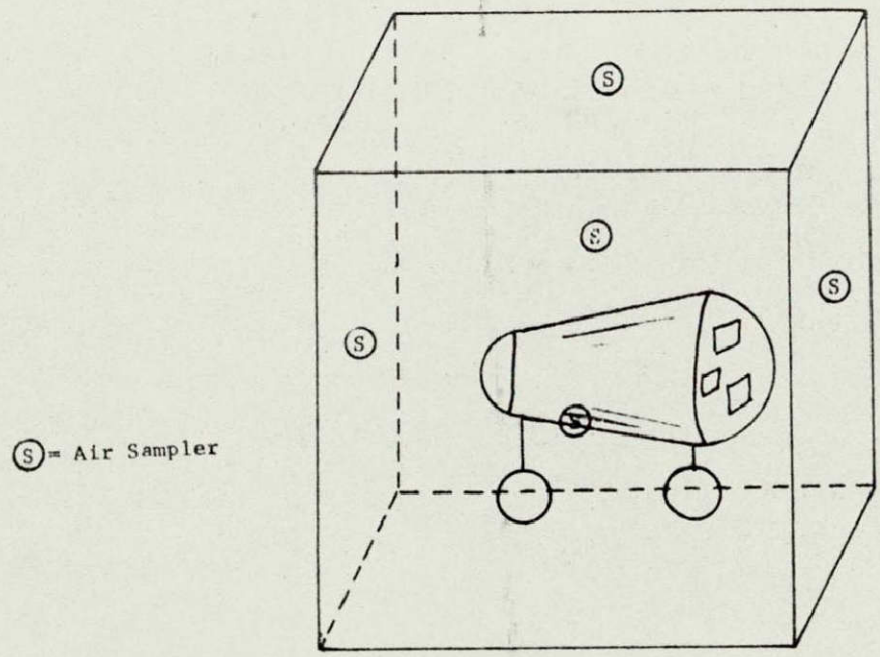


Figure 6-6. Figure Showing Orientation of Air Samplers

NASA contracting agency. Because bacterial spores are the most resistant forms to sterilization processes, it is expected that these will be of primary interest. In most manufacturing environments the aerobic sporeforms outnumber the anaerobic sporeforms. It, therefore, seems likely that anaerobic spores may not be assayed.

6.10 CERTIFICATION

6.10.1 REQUIREMENT

All equipment used in the standard operational procedures for microbiological assays will be certified either by the microbiology group or instrument calibration laboratory.

Critical operations of all equipment must be examined before any microbiological assays are performed.

All equipment should be recalibrated and certified every 6 months.

6.10.2 CERTIFICATION PLAN

Equipment normally found in a microbiological assay laboratory will be certified using the indicated guidelines.

6.10.2.1 Equipment Cerfification Guidelines

Anaerobic Incubation Jars

a. Checked for chips out of lip jar

b. The lip must be cleaned and freshly lubricated.

c. The catalyst must be certified using biological and chemical indicators.

d. The chemical indicators must be certified using known catalyst as well as vendor certification.

Andersen Sampler

a. Must meet cleanliness requirement to assure all holes are open

b. Must be leak checked to assure that the gaskets are sealing

c. Must be checked to assure the stack of sieves is in the proper order and nested properly

d. The pump must be certified to draw 1 CFM.

Assay Supplies, Disposable

a. Vendor certification on sterility (including lot numbers and results of biological tests where available).

b. Sterility test in parallel with experiment

Assay Supplies, Reuseable

a. Must be cleaned according to lab SOP's

b. Must meet laboratory sterility requirements

c. Sterility test in parallel with experiment

Autoclave

a. Certified using pressure, temperature and time read-outs

b. Must meet 15 lb psig, 250^{o}F

c. Use chemical and biological indicators in each cycle

d. Use extra thermocouples when qualifying the autoclave.

Automatic Pipetting Machine

a. Must be certified to the required volume at the temperature which the fluid will be pipetted by actual test lost time it is used

Blender Mill

a. Must be certified by the vendor

b. Must be sterility tested before an experiment

Catalyst, Cold (Anaerobic)

a. Must be certified by the vendor

b. Must be replaced in accordance with vendor certification

c. Must be checked for each experiment with chemical and biological indicators

Catalyst, Electrical (Anaerobic)

a. Must be certified by the vendor

b. Must be replaced in accordance with vendor certification

c. Must be checked for each experiment with chemical and biological indicators

Cavitation Meter

a. Certified and operated according to manufacturer's specification

Chemical Indicators, Anaerobic

a. Must be certified by the vendor

b. Must be laboratory qualified using a known catalyst and biological indicators

c. Must be limited to reuse in accordance with manufacturer's specification

Chemical Indicators, Ethylene Oxide (ETO)

a. Must be certified by the vendor

b. Must be laboratory qualified using a known ETO sterilization cycle

c. Must be limited to reuse in accordance with manufacturer's specification

Chemical Indicators, Dry Heat

a. Must be certified by the vendor

b. Must be laboratory qualified using a known dry heat sterilization cycle

Chemical Indicators, Steam

a. Must be certified by the vendor

b. Must be laboratory qualified using a known steam sterilization cycle

Chemicals

a. All chemicals will be certified by the vendor for quality and purity

Clean Bench

a. Must be leak checked using a particle counter

b. Must be checked with a velometer

c. Efficiency should be checked using a chemical smoke bomb

Clean Room

a. All filters must be leak checked.

b. Velometer reading must be taken.

c. Particle counts should be taken in accordance to NHB 5340.2.

d. Biological tests must be performed in accordance with NHB 5340.1.

e. Efficiencies must be checked and qualified for a specific limit of personnel.

Culture Media, Dehydrated

a. Must be certified by the vendor

Culture Media, Commercial Preparation

a. Must be certified by the vendor

b. Must be sterility checked in the laboratory prior to use

c. Must be qualified to support growth prior to experiment

Culture Media, Laboratory Preparation

a. Must be sterility checked in the laboratory in parallel with experiment

b. Must be qualified to support growth in parallel to experiment

Dry Glove Box

a. Must be certified by the vendor

b. Must be leak tested

c. Gloves must be leak tested.

Dry Heat Sterilizer

a. Certify using temperature and time readouts.

b. Use chemical and biological indicators in each cycle.

c. Use extra thermocouples when qualifying the sterilizer.

Ethylene Oxide Sterilizing Mixture

a. Vendor certification of each gas cylinder for:

1. Percent ethylene oxide

2. Percent Freon

3. Percent water

4. Concentration of noncompressible gases

Flow Meter

a. Vendor certified and calibrated in accordance with the National Bureau of Standards or ASTM

Gas Chromatograph

a. Calibrated and certified in accordance with the vendor supplied operating instructions

Gloves

a. Must be leak checked before use or before sterilization (the leak check procedure should be in accordance with NASA accepted procedures)

Humidity Sensor

a. Vendor certified and calibrated before and after use in accordance with the vendor-supplied operating instructions

Incubator

a. Vendor certified for temperature recovery and control

b. Must be continually monitored for temperature, using a continuous recording device

Isolator, Flexible/Rigid

a. Must be leak checked before use as a sterile barrier

b. Must be inspected daily to ensure the integrity of the barrier

c. All attachments such as gloves must be leak tested before and after attachment.

Leak Tester

a. Must be used in accordance with the vendor-supplied operating instructions

Limiting Orifice

a. Must be certified by the vendor

Manometers

a. Must be calibrated in accordance with vendor recommended procedure

Particle Counters

a. Must be certified periodically by the calibration laboratory

b. Must be operated in accordance with vendor-supplied operating instructions

Photocell, Ultraviolet

a. Must be vendor certified

Phototube, Ultraviolet

a. Must be vendor certified

pH Meter

a. Must be certified by the vendor

b. Must be checked daily when in use against known standards according to the manufacturer's operating specification

Recorders

a. Must be calibrated periodically in accordance with manufacturer's specifications

Resistivity Meter

a. Must be certified by the vendor

b. Must be checked daily when in use in accordance with vendor operating specifications

Reyniers Sampler

a. Must be certified prior to use that slit opening meets vendor's operating procedure

b. Timer must be certified.

c. Gasket must be leak checked periodically.

Rodac Plates

a. Must be certified to contain specified volume

b. Must be certified to contain proper culture medium

c. Must be sterility tested

d. Must not be used if out-dated

Stainless Steel Strips

a. Must be certified as to type of stainless, gauge and size

b. Must be certified for cleanliness

c. Must be sterility-tested

Temperature Recorders

a. Must be certified by the vendor

b. Must be calibrated according to National Bureau of Standards or ASTM

Thermocouple

a. Must be calibrated according to National Bureau of Standards or ASTM

Thermometers

a. Must be calibrated according to National Bureau of Standards or ASTM

Timers, Reyniers

a. Must be vendor certified

b. Must be calibrated according to National Bureau of Standards

Ultrasonic Bath

a. Must be certified by the vendor

b. Must be tested in accordance with the manufacturer's operating specifications

c. Must be evaluated using known biological samples

Ultraviolet Lamp

a. Must be certified by the vendor

b. Must be tested with calibrated phototubes or phototubes or photocells

Velometer

a. Must be certified by the vendor

b. Must be calibrated according to National Bureau of Standards

Water Bath

a. Must be certified by the vendor

b. Must be monitored by calibrated thermometers

Water, Distilled

a. Must be certified by the vendor

b. Must be checked for purity using a calibrated resistivity meter

6.10.2.2 Examples of Detail Certification and Checkout Information

6.10.2.2.1 Anaerobic Jars

General:

All instructions and precautions recommended by the manufacturer should be observed. (Reference: Baltimore Biological Laboratory, Division of B-D Laboratories, Inc., Baltimore, Maryland 21204)

a. Place hydrogen/carbon dioxide generator into jar. Include a red-ox color indicator and a test organism sample consisting of Alcaligenes faecalis (aerobe) and Clostridium sporogenes (anaerobe).

b. With all items in place, add 10 ml of water to the hydrogen/carbon oxide generator. Place the preheated cover (30 minutes) containing the electric catalyst in place. Tighten cover hand tight.

c. Allow reaction in anaerobic jar to run for 60 minutes at the end of 1 hour. Place anaerobic jar to run for 60 minutes at the end of 1 hour. Place anaerobic jars into incubator set at 32°C.

d. At the end of 24 hours, observe the color indicator if it has changed. The reaction has gone to completion. However, if the color indicator has not changed, open the anerobic jar and replace the catalyst (according to manufacturer's specification) and repeat the above steps.

e. If the color indicator has changed, incubate for 72 hours. At the end of this time period, remove the jars from the incubator and open them. If the streaked cultures of C. sporogenes have grown, anaerobic condition did exist in the jar during incubation. If the A. faecalis grew an aerobic condition existed in the jar.

f. To ensure the growth condition existing in the anaerobic jar at the time of incubation of the sample to be tested. Certification is required for every jar during every anaerobic incubation. If anaerobic condition does not exist in the jar, the samples tested must be discarded.

Precaution:

a. Pre-heat catalyst (covers) for 15 to 30 minutes.

b. Heat anaerobic jars (catalyst) for 1 hour for completion of the reaction.

c. Make sure covers are only hand tight so that glass jars do not crack.

d. Make sure clamps on tubing-balloon safety expansion value are lossened.

e. Always include fresh active growing cultures when testing. Do not rely solely on the color indicator.

f. Store color indicators in the refrigerator when not in use and do not touch the pocket with the hands. (Follow manufacturer's specifications.)

g. Hydrogen is generated in the jars, use regular precautions that are used with hydrogen.

All the functions and precautions are well presented by the manufacturer of the materials needed for the anaerobic jars.

6.10.2.2.2 Andersen Sieve Air Sampler

General:

All instructions and precautions by manufacturer should be observed (Reference: Andersen Samplers and Consulting Service, 1074 Ash Avenue, Provo, Utah).

a. Inspect all six stages for plugged holes in the pattern.

b. Check rate of vacuum pump to assure 1 CFM.

c. Install flow-meter down stream of sampler using tubing of recommended diameter.

d. Check gaskets between stages.

e. Assure the sample agar plates contain 27 $\pm$ 1 ml of medium (necessary for proper surface impingement).

f. Assure that plates are the special glass petri dishes recommended by Andersen.

g. Certify sampler timer.

Precautions:

a. Pour 27 $\pm$ 1 ml of culture medium in sterile Andersen petri dish placed on level surface.

b. Never cover samples with wet petri dish cover, or use plate that has wet surface.

c. Do not use vacuum tubing less than 5/16 inch (ID) or more than 5 feet long without checking flow rate in the sampling system.

d. Equilibrate prepared agar plates to room temperature (~ 25°C), after storage in refrigerator, before using them for sampling.

e. Sterilize only the sieve sampler itself, not the vacuum pump. Spring clamps should be released before sterilization.

f. Always grasp sampler firmly when releasing or connecting spring clamps so as to avoid upsetting the stack of dishes under each sieve.

g. Do not overexpose sample to the air flow. The agar will dry and crack and give incorrect results (exposures of 15 minutes/sampler are maximum).

h. Consult "Positive Hole Conversion Table" supplied with instructions when transforming colony forming units counted to correct for error.

6.10.2.2.3 Autoclave

General: All instructions and precautions recommended by the Manufacturer should be observed. (Reference: American Sterilizer Company, Erie, Pennsylvania)

a. Place liquid medium with an inoculation of a known level of bacteria. Place in autoclave as per manufacturer's recommendation. After treatment, observe sample for growth. Growth indicates improper sterilization cycle.

b. Use pressure-sensitive tape. If lines on tape change color as to manufacturer's specifications, autoclave has reached proper treatment pressure and temperature.

c. Check recording chart on sterilizer for proper temperature and time of treatment.

d. Install strategically located thermocouples to read actual temperature in the autoclave chamber.

Precautions:

a. Remove steam vent plug screen and clean debris from pores of strainer. Located in the center front of sterilizer.

b. With "Operating Handle" at "Off," turn on steam supply line value. Line pressure should be a minimum of 50 psig.

c. Sterilize only when "Jacket gauge" reads 15-17 psig.

d. "Slow exhaust" for liquids.

e. "Fast exhaust" for nonliquid samples without drying.

f. Fast exhaust and drying for materials that need drying.

g. Sterilize at 121 ^{o}C, 15 lb pressure and 15 minutes. Follow manufacturer's instructions for items to be sterilized.

h. Do not open sterilizer on liquid cycle before the temperature is below 100 ^{o}C.

6.10.2.2.4 Cross Laminar Flow Clean Bench

General:

All instructions and precautions recommended by the manufacturer should be observed.

a. Federal Standard 209A

b. NASA Standard NHB 5340.2

Precautions:

a. Check pre-filter frequently. Keep it clean and changed. This prolongs the life of the HEPA filter.

b. Turn on the bench (station) one hour before use to allow a thorough flushing of the work area.

c. Do not place dirty items upstream of samples to be tested.

d. Wipe or wash working surfaces with a sporocidal solution before performing a microbial test.

e. Clean up any spilled material before carrying out any further procedures.

6.10.2.2.5 Dry Heat Sterilizer (Oven)

General:

All instructions and precautions recommended by the manufacturer should be ovserved.

a. Adjust the desired temperature with the aid of the manufacturer's procedures and instructions.

b. Calibrate the temperature of the oven by using a calibrated thermometer or thermocouple.

c. Treat for recommended time and temperature (no less than 170^{o}C for 2 hours)

d. Perform sterility check on randomly selected items.

Precautions:

a. Allow sufficient warm-up time for the items to be sterilized. Slight overexposure to items that can be dry heat sterilized is not harmful.

b. Do not try to sterilize heat-sensitive items.

c. Loosen caps on bottles or other containers before placing them in the dry heat sterilizer.

d. Do not use paper or "stick-on" labels when using dry heat. They burn and are difficult to remove.

6.10.2.2.6 Reyniers Air Samplers

General:

All instructions and precautions recommended by the manufacturer should be observed (Reference: Procedure Pertaining to the Use of the Mechanical Interval Timer Slit Sampler, Reyniers & Son, 3806 N. Ashland Avenue, Chicago, Illinois).

a. Check width of slit opening 0.006 in.

b. Sampling Rate 1 CFM

c. Wind timer, timer switch off

d. Flowmeter down stream of sampler

e. Inspect and clean slit opening.

f. Inspect gasket.

g. Use glass petri dish of appropriate agar.

h. Adjust height of slit above agar (2 to 3 mm).

i. Adjust vacuum to operate at 1 CFM.

j. Timer must be certified prior to sampling.

Precautions:

a. Sampler bottom containing the timer cannot be steam sterilized.

b. The sampler top need only be sterilized.

c. The sampler top need not be sterilized for consecutive samples.

d. Check all openings for leaks before sampling.

6.10.2.2.7 Ultrasonic Bath

General:

All instructions and precautions recommended by the manufacturer should be observed.

a. The ultrasonic cleaner should be calibrated (preferably by a factory representative).

b. A quick check of the effective energy is to place a sheet of standard household aluminum foil on the bottom of the tank (if the transducers are on the bottom). Turn on the ultrasonic cleaner and observe the foil. If it erodes evenly, the energy is relatively equal throughout that area. If it is unequal, a qualified factory representative should be consulted.

Precautions

a. When treating liquid sample, keep the caps loose to allow for outgassing of the sample.

b. Do not exceed the limitation or attempt to use the ultrasonic unit for a job for which it is not designed.

c. Ensure that the bath liquid level is one inch above that of the sample liquid level

d. The instruction included with the unit should be read thoroughly before trying to operate the ultrasonic cleaner.

6.10.3 DOCUMENTATION

Quality Assurance activity will indicate that the equipment has been certified by the use of a tag or stamp appropriately displayed on the item certified.

A documentation form will also be maintained by Quality Assurance indicating:

a. The date the equipment was last certified

b. The certifying agency

c. The critical parameters calibrated or tested

d. The Quality Assurance inspector who verified the certification

6.11 RECEIVING INSPECTION OF MICROBIOLOGICAL MATERIALS

This subsection covers, guidelines, and requirements to be used in a microbiological materials receiving inspection operation. It will assure that materials procured and stocked will meet the applicable quality documents. To provide this assurance, all received materials will be subjected to inspection and/or tests to assure conformance to the applicable requirements and standards. These inspection/tests will include visual, physical and chemical, and microbiological requirements. Some of these requirements will be met through vendor certification or detailed experiments carried out in the microbiological assay laboratory. All receiving inspection documentation such as test and inspection data, defect trends, failure data, and nonconforming material will be compiled in a central data bank.

6.11.1 IDENTIFICATION

6.11.1.1 Objectives

The objectives of the identification task are;

a. To control the identities of all microbiological laboratory supplies and materials which are received by Receiving Inspection.

b. To identify that all shipments received meet the procurement request

6.11.1.2 Requirements

To accomplish these objectives the receiving inspection activity will:

a. Maintain an inspection control stamp which will be identifiable as receiving inspection identification

b. Stamp all purchase orders and indicate the completeness and correctness, of the shipment received

c. Note any deviations of the procurement request on an "Inspection Data Report" which will be entered into a central data bank

6.11.2 VISUAL ANALYSIS

6.11.2.1 Objectives

The objectives of the visual analysis task is to assure:

a. That all incoming microbiological supplies arrive with no physical change

b. That all packages and materials marked "sterile" are properly sealed

c. That all items are properly identified

6.11.2.2 Requirements

To accomplish these objectives the receiving activity will:

a. Maintain an inspection control stamp which will be identifiable as receiving inspection visual analysis

b. Stamp all materials following inspection

c. Visually inspect all sealed containers and verify that all packages marked STERILE have not been opened.

d. Verify that "tamper proof" seals are intact.

e. Visually inspect all materials and supplies for improper handling.

f. Verify that any required vender certification accompany the materials.

g. Submit "Visual Analysis Nonconformance Report" to central data bank.

Procedures will be established for handling material which has been damaged, contaminated, or suspected of being contaminated.

6.11.3 PHYSICAL AND CHEMICAL PROPERTIES ANALYSIS

6.11.3.1 Objectives

The objective of the physical and chemical properties analysis receiving inspection activity is to assure that the materials received conform with the applicable quality documents.

6.11.3.2 Requirements

To accomplish these objectives, vender certification will be required on all necessary microbiological laboratory supplies and materials. Inspection will only be of a visual analysis nature to verify that the necessary vender-supplied documents accompany the materials

6.11.4 MICROBIOLOGICAL ANALYSIS

6.11.4.1 Objectives

The objectives of the microbiological analysis of the receiving inspection activity will be to assure that microbiological laboratory supplies and materials received conform to the applicable quality documents.

6.11.4.2 Requirements

To accomplish these objectives, random supplies will be selected from the materials and will be certified for sterility, viability, or ability to support growth through extensive laboratory experiments. Acceptibility and Nonconformance Reports will be submitted to the central data bank.

6.12 DATA AND REPORT REQUIREMENTS

6.12.1 OBJECTIVES

A system of data gathering, storage and reporting will be established to assure that all test data and results are available and disseminated to all interested parties using the most rapid practical means available.

6.12.2 REQUIREMENTS

A system of data gathering, storage, and dissemination shall be established to assure that:

a. The status of each microbiological assay is available

b. The latest test procedures (SOP's) are available for the assay

c. The necessary people are cognizant to the test results in a timely and efficient manner

d. Pertinent data is available for all of the microbiological assays and that such data may be extracted, reduced or summarized at a later date

e. The microbiological history is maintained on all assayed hardware items

f. Significant data is available for microbial burden assessment, reliability and microbiological analysis

g. Timely and effective feedback to the Sterility Control Board, NASA Planetary Quarantine Officer, and cognizant engineering groups through the Data System.

The system devised for the above shall be consistent with the following requirements:

a. A log containing pertinent data on each microbiological assay will be maintained by the microbiological testing group.

b. Maximum use will be made of the integrated data storage and retrieval system for the storage and dissemination of data.

c. Data requirements will be coordinated with all data users.

d. The number of forms and reports required for processing items will be minimized by coordinating needs with other groups.

e. The system used will be consistent with the overall integrated data storage and retrieval plan with regard to format and coding as required by the Data System (Section 2.10).

f. All data and reports will be available for review by the Sterility Control Board and/or the NASA Planetary Quarantine Officer upon request.

6.12.3 DATA CATEGORIES

The data falls into two general categories, test data and inspection data.

6.12.3.1 Test Data

The test data consists of that information which is collected by the microbiological group relevant to microbiological assays. This data will be collected from two general sources: (1) the intramural environment and the personnel to which the test item will be exposed and (2) the hardware itself. All information will be recorded on standard data forms.

6.12.3.1.1 Environmental and Personnel Data

Data should be collected from all the major parameters of the test environment. The intramural environment should be sampled for airborne microbial particulates, contamination which accumulates on surfaces, as well as support equipment and hardware, tools and personnel who will be working in the facility.

6.12.3.1.2 Hardware Data

Data should be collected from all hardware, including piece parts, subsystems, and vehicles. The piece parts should be assayed for total count. Large items such as systems will only

be fractionally sampled over a relatively small portion of the total item. A sufficient number of samples will have to be taken to ensure statistically significant data. A sampling plan for specific hardware will be written before any testing. The raw data will be reduced into usable form and put into the data bank and ultimately into a computer math model.

6.12.3.1.3 Microbiological Data

The raw data should be collected and recorded on standard data sheets (see Appendix A, Figures A-1 through A-15) Microorganisms should be differentiated between aerobic and anaerobic forms and between vegetative cells and spores. Colony counts should be made at 24, 48 and 72 hours $\pm$5 hours. These counts should be reported in colony forming units, unit area, or unit volume. A colony forming unit will be considered to be a least one viable microorganism.

The supplementary data should be collected and recorded on standard data forms (see Appendix Figures A-7 through A-15). The following information should be included in this category:

a. Title of microbiological assay

b. Date

c. Facility

d. Sample technique and description

e. Sterility check on all necessary supplies and equipment

f. Verification that all utilized equipment was prepared according to applicable SOP's

g. Verification of all sample treatments

h. Time in which assay was carried out

i. Incubation condition (temperature, aerobic and anaerobic)

j. Verification of anaerobic incubation conditions (if applicable)

k. Sample code and identification

l. Signed off by the performing technician, supervising microbiologist and Quality Assurance Surveillance

Figure A-16 presents a flow chart illustrating the procedure for data reduction.

6.12.3.2 Inspection Data

The inspection data consists of that information which is collected by the quality surveillance group relevant to microbiological assays.

6.12.3.2.1 Check Lists

6.12.3.2.1.1 General Guidelines This section is for the guidance of Quality Assurance management and supervision to assure that Quality Assurance procedures and directives provide adequate guidance to Quality Assurance personnel on the microbiology requirements and assure that Quality Assurance supervision is monitoring activities for compliance with Microbial Contamination Control standards and requirements.

a. Have Quality Assurance supervision, inspection and audit personnel received and completed Sterilization and Microbial Contamination Control indoctrination and training?

b. Have copies of applicable Sterilization and Microbial Contamination Control documents been made available to Quality Assurance personnel?

c. Are standardized reporting forms being utilized by Quality Assurance?

d. Have interface communication channels between Microbiology and Quality Assurance been established and have responsible personnel been designated?

e. Do Quality Assurance procedures and manuals establish requirements, reporting channels and methods for microbiological contamination control?

f. Are all events or incidents of contamination affecting the microbiological burden of major end items being recorded, reported and corrected in coordination with microbiologists and NASA Planetary Quarantine officers?

g. Are Quality Assurance personnel preparing Problem Action Records (PAR) on actual potential contamination problems, conditions, or deviations in procedures?

h. Are periodic surveys of manufacturing and test facilities being made for potential contamination problems or conditions?

i. Is Quality Assurance participating in a Contamination Control Review Board or Sterility Control Group?

j. Are separate corrective action lists of microbiological items requiring corrective action being maintained and coordinated with the microbiologists and NASA Planetary Quarantine officer?

k. Are potential microbiological contamination problems being emphasized in management staff meetings and work scheduling meeting?

l. Are contamination briefings of Quality Assurance personnel being conducted periodically?

6.12.3.2.1.2 General Requirements - Checklists are working aids for Quality Assurance procedures and personnel involved in a spacecraft sterilization program. They are specifically designed for use by Quality personnel to assure that sterilization requirement standards and criteria are considered and emphasized during Quality Assurance inspection and audits.

The purpose of such checklists is to aid in the prevention of contamination violations, resulting in deposition of microorganisms on hardware to be sterilized as well as to assure that microbiological test procedures are performed according to previously established SOP's. These check lists have been designed to emphasize attention to microbiology contamination control standards and critieria during procurement, manufacture, testing, packaging, storage and transport. It is intended for use by Quality Control personnel as they perform their normal function on a program and should be supplemented by additional control requirements as necessary for application in conjunction with normal inspection functions.

Checklists should be prepared by Quality Assurance inspection for all microbiologically oriented procedures. These will follow the standard operating procedures which are written by the microbiology group.

Activities which should be monitored using Quality Assurance checklists include:

a. Sampling of all laboratory materials

b. Clean room dressing procedure

c. Decontamination processes

    1. Applicable laboratory supplies and equipment

    2. Assembly tools

    3. Subassembly units

d. All assembly operations;

    1. Microbiological sampling

    2. Laboratory techniques

    3. All normal activity

e. Microbiological samples for statistical requirements

    1. Stainless steel coupon allotment

    2. Swab samples

    3. Hardware items

    4. Air samples

6.12.3.2.2 Procurement Checklists

This section provides guidance for Quality Assurance personnel engaged in planning and monitoring of procurement functions on a sterilization program. It includes monitoring of

procurement specification and subcontractor or vendor activities for compliance with the Program microbiological requirements.

a. Have microbiological requirements been considered during source selection inspections?

b. Are procurement specifications being reviewed for microbiological requirements, standards, and criteria?

c. Have reporting forms or procedures been established for reporting of microbial contamination levels from vendor plants?

d. Are vendor products being inspected for compliance with end item microbial contamination levels?

e. Are vendor storage, handling and packaging procedures reviewed for microbial burden requirements?

f. Is packaging of products periodically inspected for microbiological integrity to prevent contamination of the parts?

g. Are contaminated materials promptly reported to the microbiologist and NASA Planetary Quarantine Officer?

h. Are process specifications for cleaning, handling, decontamination and storage of parts reviewed for microbiology requirements?

6.12.3.2.3 Facilities Checklists

This section provides guidelines for the inspection and control of any facility in which bio-clean hardware is being handled. The facilities should be constantly monitored by Quality Assurance personnel.

a. Are all test facilities (clean rooms) contamination control devices adequate and operational?

b. Are tests being conducted within facility activity design limits?

c. Are there adequate safeguards to prevent excessive contamination of the facility either through personnel or equipment failure?

d. Are procedures available for test or manufacture shut-down if any facilities fail?

e. Are there defined contamination limits which yield facility failure?

f. Are the different processes which are carried out in the same facility compatible from the comtamination control aspect?

g. Is the facility controlled to ensure that only authorized personnel are admitted into the controlled areas?

h. Are the minimum recommended tests for microbial load conducted on schedule?

i. Does the facility have adequate housekeeping procedures?

j. Are there positive cleanliness controls on hardware and materials being brought into work areas?

k. Are procedures used for control of cleaned, decontaminated or sterilized parts adequate?

l. Are all critical personnel certified to participate in a Planetary Quarantine/Spacecraft Sterilization Program?

m. Are adequate safety measures taken in clean rooms?

6.12.3.2.4 Operations Control Check Lists

This section provides general guidelines related to methods, practices and procedures for control of comtamination for all operations. Quality Assurance personnel will observe all operations and submit reports to Quality Assurance supervisior, microbiology, Sterility Control Group and NASA Planetary Quarantine Officer.

a. Has supervisory responsibility for conduct of operation been clearly designated?

b. Are tests performed in accordance with written and approved standard operation procedures?

c. Is all unplanned work being adequately documented?

d. Are supplementary personnel (i.e., janitorial, safety and security) properly indoctrinated on contamination control and clean room procedures?

e. Have provisions been made for assuring information transfer during shift changes?

f. Are personnel required to work excessive overtime (more than 12 hours continuous or more than 18 hours in a 24-hour period)?

g. Do personnel follow written test procedures?

h. Are deviations from test procedures documented?

i. Is unnecessary equipment prohibited from entering the controlled facility?

j. Does approval of test procedures include microbiology and engineering?

6.12.3.2.5 Transportation and Handling Checklists

This section provides general guidelines for handling, packaging and transportation of contamination controlled hardware. Quality Assurance personnel should monitor all these activities.

a. Is each transportation and handling operation governed by specific written procedures?

b. Is the integrity of the packaging barrier (microbial-barrier) monitored during and following handling and transportation?

6.12.3.3 Acceptance Data

All acceptance data collected by Quality Assurance will be appropriately indicated on the microbiological assay data sheets. This may be accomplished by a stamp or signature of the Quality Assurance inspector.

6.12.4 DATA CODING

6.12.4.1 Objectives

The objective of data coding is to supply all the information necessary to identify a sample if it has been removed from the context of the data book.

6.12.4.2 Requirements

The requirements for adequate data coding and identification are twofold:

a. Data Master Code Book - A data master code book must be kept separate from the data book. This master code book will have listed in it every microbiological assay performed by the microbiological group. It will contain the following information:

1. The date of the assay and assay number
2. The sampling technique used
3. The item assayed
4. The number of assays performed on that item and their codes
5. Name of the microbiologist who performed the assay

b. Data Book Coding - The data book will be arranged so that each individual sample has a single page on which all colony counts will be recorded. The additional coding on the data page will consist of the following:

1. Assay number or designation
2. Sample dilution
3. Sample incubation conditions (aerobic or anaerobic)
4. The type of microbial cells (vegetative, spores), (bacteria, or fungi)
5. The actual colony counts (24, 48 and 72 hours)

6.12.4.3 Data Formats

The objective of the data format is to allow input into a computer for either data storage or analysis. The format will be dependent of the computer system used.

APPENDIX A

TYPICAL DATA SHEETS

ANDERSEN SAMPLER DATA SHEET

FACILITY: _____ DATE: _____

EXPERIMENTER: (INITIAL) _____

TYPE OF INCUBATION: AEROBIC 32°C CO-SIGNER: (INITIAL) _____ DATE: _____

INCUBATION TIME		24 HRS.		48 HRS.		72 HRS.		CORRECTED COUNT (ANDERSEN CONVERSION TABLE)	VIABLE PARTICLES PER FT.^{3} AIR
TYPE OF MICROORGANISM		BACTERIA	MOLDS	BACTERIA	MOLDS	BACTERIA	MOLDS		
CODE	STAGE								
	A-1								
	-2								
	-3								
	-4								
	-5								
	-6								
	TOTAL								
	B-1								
	-2								
	-3								
	-4								
	-5								
	-6								
	TOTAL								
	C-1								
	-2								
	-3								
	-4								
	-5								
	-6								
	TOTAL								
COLUMN KEY		a	b	c	d	e	f		

TIME OF OPERATION: A - ON: _____ OFF: _____ TOTAL TIME: _____ MIN.
B - ON: _____ OFF: _____ TOTAL TIME: _____ MIN.
C - ON: _____ OFF: _____ TOTAL TIME: _____ MIN.

(Revised 9/68)

Figure A-1. Andersen Sampler Data Sheet

ANDERSEN SAMPLER DATA SHEET

FACILITY: _____ DATE: _____

EXPERIMENTER: _____

CO-SIGNER: _____

TYPE OF INCUBATION: ANAEROBIC 32°C DATE: _____

INCUBATION TIME		72 HOURS	CORRECTED COUNT (ANDERSEN CONVERSION TABLE)	VIABLE PARTICLES PER FT.^{3} AIR
TYPE OF MICROORGANISM		BACTERIA		
CODE	STAGE			
	D-1			
	-2			
	-3			
	-4			
	-5			
	-6			
TOTAL				
COLUMN KEY		g		

TIME OF OPERATION: D - ON: _____ OFF: _____ TOTAL TIME: _____MIN.

COMMENTS:

(Revised 9/68)

Figure A-2. Andersen Sampler Data Sheet

FALLOUT PLATES - DATA SHEET

FACILITY: _____ DATE: _____

EXPERIMENTER: _____

CO-SIGNER: _____

DATE: _____

TIME OF EXPOSURE: OPEN: _____ CLOSED: _____ TOTAL TIME: _____ MIN.

TYPE OF INCUBATION		AEROBIC						ANAERO.
INCUBATION TIME		24 HOURS		48 HOURS		72 HOURS		72 HOURS
TYPE OF MICROORGANISMS		BACTERIA	MOLDS	BACTERIA	MOLDS	BACTERIA	MOLDS	BACTERIA
AREA (LOCATION)	CODE							

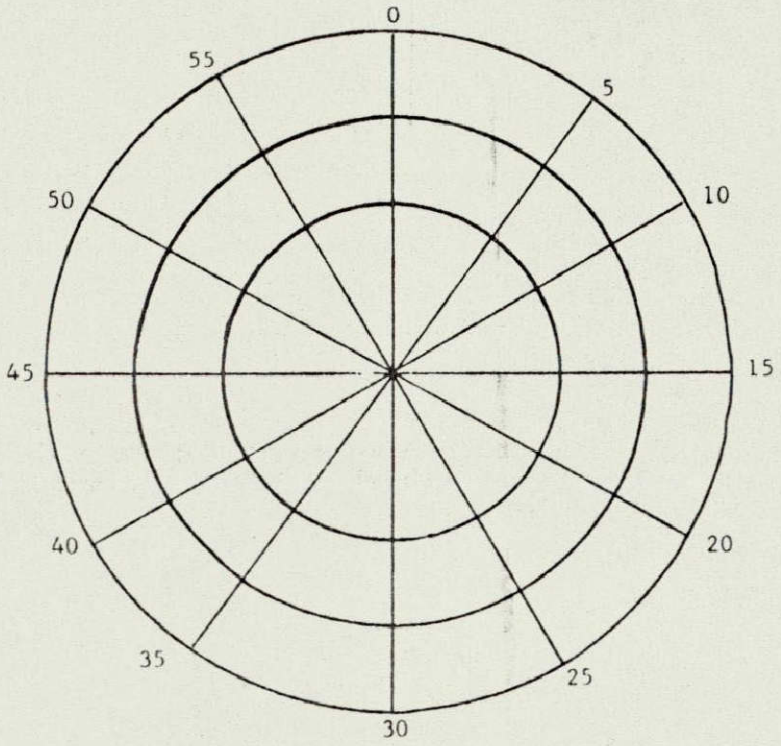
(Revised 9/68)

Figure A-3. Fallout Plates - Data Sheet

REYNIERS SAMPLER DATA SHEET

NOTE

(1) 24 hour counts are recorded in the inner circle.
(2) 48 hour counts are recorded in the middle circle.
(3) 72 hour counts are recorded in the outer circle.



DATE: _____ EXPERIMENTER: _____

(1) FACILITY: _____

(2) TIME OF OPERATION - ON: _____ OFF: _____ TOTAL TIME: _____

SAMPLE INCUBATION: AEROBIC TEMPERATURE: 32°C

REMARKS:

(Revised 9/68)

Figure A-4. Reyniers Sampler - Data Sheet

RODAC PLATE SAMPLES OF ENVIRONMENTAL SURFACES
DATA SHEET

FACILITY: _____ DATE: _____

EXPERIMENTER (INITIAL): _____

CO-SIGNER (INITIAL): _____ DATE: _____

TYPE OF INCUBATION		AEROBIC				ANAEROBIC
INCUBATION TIME		24 HOURS		72 HOURS		72 HOURS
TYPE OF MICROORGANISMS		BACTERIA	MOLDS	BACTERIA	MOLDS	BACTERIA
WORK AREA SAMPLED	CODE					
COLUMN KEY		a	b	c	d	e

(Revised 9/68)

Figure A-5. Rodac Plate Samples of Environmental Surfaces Data Sheet

STAINLESS STEEL STRIP SAMPLING - DATA SHEET

DATE: _____

EXPERIMENTER: (INITIAL) _____

CO-SIGNER: (INITIAL) _____

DATE: _____

STAINLESS STEEL STRIP NUMBER: _____

		NON-HEAT SHOCK SAMPLES								HEAT SHOCK SAMPLES			
INCUBATION CONDITIONS		AEROBIC						ANAEROBIC		AEROBIC		ANAEROBIC	
SAMPLE		STRIP		FIRST 5 ml		SECOND 5 ml		THIRD 5 ml	FOURTH 5 ml	FIFTH 5 ml	SIXTH 5 ml	SEVENTH 5 ml	EIGHTH 5 ml
VISIBLE TYPE OF MICROORGANISMS		BACTERIA	MOLD	BACTERIA	MOLD	BACTERIA	MOLD	BACTERIA	BACTERIA	BACTERIA	BACTERIA	BACTERIA	BACTERIA
INCUBATION TIME	24 HRS.												
	48 HRS.												
	72 HRS.												
COLUMN KEY		a	b	c	d	e	f	g	j	m	p	t	w

(Revised 9/68)

Figure A-6. Stainless Steel Strip Sampling Data Sheet

SWAB SAMPLE DATA SHEET

FACILITY: _____ DATE: _____ EXPERIMENTER (INITIAL): _____

CO-SIGNER (INITIAL): _____

DATE: _____

INCUBATION CONDITIONS		NON-HEAT SHOCK							HEAT SHOCK			
		AEROBIC						ANAERO.	AEROBIC			ANAERO.
ALIQUOT		1st 1 ml						2nd 1ml	3rd 1 ml			4th 1ml
INCUBATION TIME		24 HRS.		48 HRS.		72 HRS.		72 HRS.	24 HRS.	48 HRS.	72 HRS.	72 HRS.
VISIBLE TYPE OF MICROORGANISMS		BACT.	MOLDS	BACT.	MOLDS	BACT.	MOLDS	BACT.	BACT.	BACT.	BACT.	BACT.
SAMPLE	CODE											
COLUMN KEY		a	b	c	d	e	f	g	i	m	p	t

(Revised 9/68)

Figure A-7. Swab Sample Data Sheet

TITLE: Intermittent Volumetric Intramural Air Sample - Andersen Sampler DATE: _____

FACILITY: _____ _____

SAMPLE DURATION: _____

	DATE TESTED	CHECK	INITIAL
I. Verify the following Sterility Qualification tests.			
(1) Andersen Plates	_____	____	
II. Verify the following equipment prepared according to specific SOP's.			
(1) Clean Bench - SOP #48		____	
(2) Andersen Plates - SOP #19		____	
(3) Andersen Sampler - SOP #28		____	
(4) Aerobic Incubator - SOP #34		____	
(5) Anaerobic Incubator - SOP #35		____	
III. Verify the following treatments			
(1) Samples taken according to SOP #9		____	
(2) Incubation Temperature			
0 TIME _____ °C			____
24 HOURS _____ °C			____
48 HOURS _____ °C			____
72 HOURS _____ °C			____
(3) Anaerobic Incubation Condition			
Chemical Indicator			
24 Hours White ( ) Blue ( )			____
72 Hours White ( ) Blue ( )			____

(Revised 9/68)

Figure A-8. Intermittant Volumetric Intramural Air Sample - Andersen Sampler (Sheet 1 of 2)

TITLE: Intermittent Volumetric Intramural Air Sample - Andersen Sampler DATE: _____

	DATE TESTED	CHECK	INITIAL
Microbial Indicators			
Alcaligenes faecalis			
72 HOURS + ( ) - ( )			_____
Clostridium sporogenes			
72 HOURS + ( ) - ( )			_____

+ = Growth

- = No Growth

COMMENTS:

TECHNICIAN: _____ DATE: _____

MICROBIOLOGIST: _____ DATE: _____

Q/A SURVEILLANCE: _____ DATE: _____

(Revised 9/68)

Figure A-8. Intermittant Volumetric Intramural Air Sample-Andersen Sampler (Sheet 2 of 2)

TITLE: Gravimetric Air Sample - Agar Fallout Plates DATE: _____

FACILITY: _____

SAMPLE DURATION: _____

	DATE TESTED	CHECK	INITIAL
I. Verify the following Sterility Qualification tests.			
(1) Agar Fallout Plates	_____	____	
II. Verify the following equipment prepared according to specific SOP's.			
(1) Clean Bench - SOP #48		____	
(2) Fallout Plates - SOP #11		____	
(3) Aerobic Incubator - SOP #34		____	
(4) Anaerobic Incubator - SOP #35		____	
III. Verify the following treatments.			
(1) Samples taken according to SOP #1		____	
(2) Incubator Temperatures			
0 TIME _____ °C			____
24 HOURS _____ °C			____
48 HOURS _____ °C			____
72 HOURS _____ °C			____
(3) Anaerobic Incubation Conditions			
Chemical Indicator			
24 HOURS White ( ) Blue ( )			____
72 HOURS White ( ) Blue ( )			____

(Revised 9/68)

Figure A-9 . Gravimetric Air Sample - Agar Fallout Plates (Sheet 1 of 2)

TITLE: Gravimetric Air Sample - Agar Fallout Plates PAGE 2

	DATE TESTED	CHECK	INITIAL
Microbiological Indication			
Alcaligenes faecalis			
72 HOURS + ( ) - ( )			_____
Clostridium sporogenes			
72 HOURS + ( ) - ( )			_____

\+ = Growth

\- = No Growth

COMMENTS:

TECHNICIAN: _____ DATE: _____

MICROBIOLOGIST: _____ DATE: _____

Q/A SURVEILLANCE: _____ DATE: _____

(Revised 9/68)

Figure A-9. Gravimetric Air Sample - Agar Fallout Plates (Sheet 2 of 2)

TITLE: Sequential Volumetric Intramural Air Sample - Reyniers Sampler DATE: _____

FACILITY: _____

SAMPLE DURATION: _____

	DATE TESTED	CHECK	INITIAL
I. Verify the following Sterility Qualification Tests:			
(1) Reyniers Plates	_____	____	
II. Verify the following equipment prepared according to specific SOP's.			
(1) Clean Bench - SOP #48		____	
(2) Reyniers Plates - SOP #21		____	
(3) Reyniers Sampler - SOP #29		____	
(4) Aerobic Incubator - SOP #34		____	
III. Verify the following treatments.			
(1) Samples taken according to SOP #8		____	
(2) Aerobic Incubation Temperature			
0 TIME _____ °C			_____
24 HOURS _____ °C			_____
48 HOURS _____ °C			_____
72 HOURS _____ °C			_____

COMMENTS:

TECHNICIAN: _____ DATE: _____

MICROBIOLOGIST: _____ DATE: _____

Q/A SURVEILLANCE: _____ DATE: _____

(Revised 9/68)

Figure A-10. Sequential Volumetric Intramural Air Sample - Reyniers Sampler

TITLE: Rodac Plate Sampling of Environmental Surfaces DATE: _____

FACILITY: _____

	DATE TESTED	CHECK	INITIAL
I. Verify the following Sterility Qualification Tests.			
(1) Rodac Plates	_____	____	
II. Verify the following equipment prepared according to specific SOP's.			
(1) Aerobic Incubator - SOP #34		____	
(2) Anaerobic Incubator - SOP #35		____	
III. Verify the following treatments.			
(1) Samples taken according to SOP #6.		____	
(2) Samples held between 25 and 35°C.		____	
(3) Samples incubated within ____ hours after collection:			
Incubation Time: _____			
Collection Time: _____			
Difference: _____			____
(4) Incubation Temperature			
0 TIME _____ °C			____
24 HOURS _____ °C			____
72 HOURS _____ °C			____
(5) Anaerobic Incubation Conditions			
Chemical Indicator - 24 HOURS White ( ) Blue ( )			____
72 HOURS White ( ) Blue ( )			____

(Revised 9/68)

Figure A-11. Rodac Plate Sampling of Environmental Surfaces (Sheet 1 of 2)

DATE TESTED CHECK INITIAL

Microbial Indicator

Alcaligenes faecalis - 72 HOURS

+ ( ) - ( ) _____

Clostridium sporogenes - 72 HOURS

+ ( ) - ( ) _____

+ = Growth
- = No Growth

COMMENTS:

TECHNICIAN: _____ DATE: _____

MICROBIOLOGIST: _____ DATE: _____

Q/A SURVEILLANCE: _____ DATE: _____

(Revised 9/68)

Figure A-11. Rodac Plate Sampling of Environmental Surfaces (Sheet 2 of 2)

TITLE: Stainless Steel Strip Sampling Environmental DATE: _____

FACILITY: _____

SAMPLE DURATION: _____

STRIP TYPE: (Circle One) 16 Gauge 23 Gauge

	DATE TESTED	CHECK	INITIAL
I. Verify the following Sterility Qualification Tests:			
(1) Forceps	_____	____	
(2) Sample Bottles	_____	____	
(3) Peptone Water	_____	____	
II. Verify the following equipment prepared according to specific SOP's.			
(1) Clean Bench - SOP #48		____	
(2) Ultrasonic Cleaner - SOP #26		____	
(3) Heat Shock Water Bath - SOP #63		____	
(4) Aerobic Incubator - SOP #34		____	
(5) Anaerobic Incubator - SOP #35		____	
III. Verify the following treatments.			
(1) Samples removed from trays according to SOP #61.		____	
(2) Samples held between 25 and 35°C.		____	
(3) Ultrasonic treatment for 2 minutes.		____	
(4) Heat shock treatment 25 ml - 80 $\pm 2^{\circ}$C for 20 minutes.		____	

(Revised 9/68)

Figure A-12. Stainless Steel Strip Sampling-Environmental (Sheet 1 of 3)

TITLE: Stainless Steel Strip Sampling - Environmental PAGE 2

	DATE TESTED	CHECK	INITIAL
(5) Samples assayed within _____ hours after collection.			
Assay Completion Time: _____			
Collection Time: _____			
Difference: _____			_____
(6) Incubation Temperature			
0 TIME _____ °C			_____
24 HOURS _____ °C			_____
48 HOURS _____ °C			_____
72 HOURS _____ °C			_____
(7) Anaerobic Incubation Conditions			
Chemical Indicator			
24 HOURS White ( ) Blue ( )			_____
72 HOURS White ( ) Blue ( )			_____
Microbial Indicator			
Alcaligenes faecalis			
72 HOURS + ( ) - ( )			_____
Clostridium sporogenes			
72 HOURS + ( ) - ( )			_____

+ = Growth
- = No Growth

TRAY LOCATION:

STRIP NUMBERS:

(Revised 9/68)

Figure A-12. Stainless Steep Strip Sampling-Environmental (Sheet 2 of 3)

TRAY LOCATION:

STRIP NUMBERS:

TRAY LOCATION:

STRIP NUMBERS:

TRAY LOCATION:

STRIP NUMBERS:

COMMENTS:

TECHNICIAN: _____ DATE: _____

MICROBIOLOGIST: _____ DATE: _____

Q/A SURVEILLANCE: _____ DATE: _____

(Revised 9/68)

Figure A-12. Stainless Steel Strip Sampling-Environmental (Sheet 3 of 3)

TITLE: Stainless Steel Strip Sampling DATE: _____

HARDWARE: _____

SAMPLE TREATMENT: _____

STRIP TYPE: (Circle One) 16 Gauge 23 Gauge

	DATE TESTED	CHECK	INITIAL
I. Verify the following Sterility Qualification Tests:			
(1) Forceps	_____	____	
(2) Sample Bottles	_____	____	
(3) Peptone Water	_____	____	
II. Verify the following equipment prepared according to specific SOP's.			
(1) Clean Bench - SOP #48		____	
(2) Ultrasonic Cleaner - SOP #26		____	
(3) Heat Shock Water Bath - SOP #63		____	
(4) Aerobic Incubator - SOP #34		____	
(5) Anaerobic Incubator - SOP #35		____	
III. Verify the following treatments:			
(1) Samples removed from hardware according to SOP #60.		____	
(2) Samples held between 25 and 35°C		____	
(3) Ultrasonic treatment for 2 minutes		____	
(4) Heat shock treatment 25 ml - 80 $\pm$2°C for 20 minutes.		____	

(Revised 9/68)

Figure A-13. Stainless Steel Strip Sampling (Sheet 1 of 3)

	DATE TESTED	CHECK	INITIAL
(5) Samples assayed within ___ hours after collection.			
Assay Completion Time: _____			
Collection Time: _____			
Difference: _____			_____
(6) Incubation Temperature			
0 TIME _____ °C			_____
24 HOURS _____ °C			_____
48 HOURS _____ °C			_____
72 HOURS _____ °C			_____
(7) Anaerobic Incubation Conditions			
Chemical Indicator			
24 HOURS White( ) Blue ( )			_____
72 HOURS White( ) Blue ( )			_____
Microbial Indicator			
Alcaligenes faecalis			
72 HOURS + ( ) - ( )			_____
Clostridium sporogenes			
72 HOURS + ( ) - ( )			_____

+ = Growth
- = No Growth

HARDWARE:

STRIP NUMBERS:

(Revised 9/68)

Figure A-13 Stainless Steel Strip Sampling (Sheet 2 of 3)

COMMENTS:

TECHNICIAN: _____ DATE: _____

MICROBIOLOGIST: _____ DATE: _____

Q/A SURVEILLANCE: _____ DATE: _____

(Revised 9/68)

Figure A-13. Stainless Steel Strip Sampling (Sheet 3 of 3)

TITLE: Swab Rinse Samples of Surfaces DATE: _____

FACILITY: _____

	DATE TESTED	CHECK	INITIAL
I. Verify the following Sterility Qualification Tests.			
(1) Swabs	_____	____	
(2) 5 ml of 1% Peptone			
II. Verify the following equipment prepared according to specific SOP's.			
(1) Clean Bench - SOP #48		____	
(2) Ultrasonic Cleaner - SOP #26		____	
(3) Heat Shock Bath - SOP #63		____	
(4) Aerobic Incubator - SOP #34		____	
(5) Anaerobic Incubator - SOP #35		____	
III. Verify the following treatments.			
(1) Samples taken according to SOP #7.		____	
(2) Ultrasonic treatment for 2 minutes.		____	
(3) Heat Shock Treatment - 80°C ±2°C for 20 min.		____	
(4) Samples assayed with ___ Hours after collection.			
Assay Completion Time: _____			
Collection Time: _____			
Difference: _____			____
(5) Incubation Temperature			
0 TIME _____ °C			____
24 HOURS _____ °C			____
48 HOURS _____ °C			____
72 HOURS _____ °C			____

(Revised 9/68)

Figure A-14. Swab Rinse Samples of Surfaces (Sheet 1 of 2)

	DATE TESTED	CHECK	INITIAL
(6) Anaerobic Incubation Conditions			
Chemical Indicator			
24 HOURS WHITE ( ) BLUE ( )			_____
72 HOURS WHITE ( ) BLUE ( )			_____
Microbial Indicator			
Alcaligenes faecalis			
72 HOURS + ( ) - ( )			_____
Clostridium sporogenes			
72 HOURS + ( ) - ( )			_____
+ = Growth			
- = No Growth			

COMMENTS:

TECHNICIAN: _____ DATE: _____

MICROBIOLOGIST: _____ DATE: _____

Q/A SURVEILLANCE: _____ DATE: _____

(Revised 9/68)

Figure A-14. Swab Rinse Samples of Surfaces (Sheet 2 of 2)

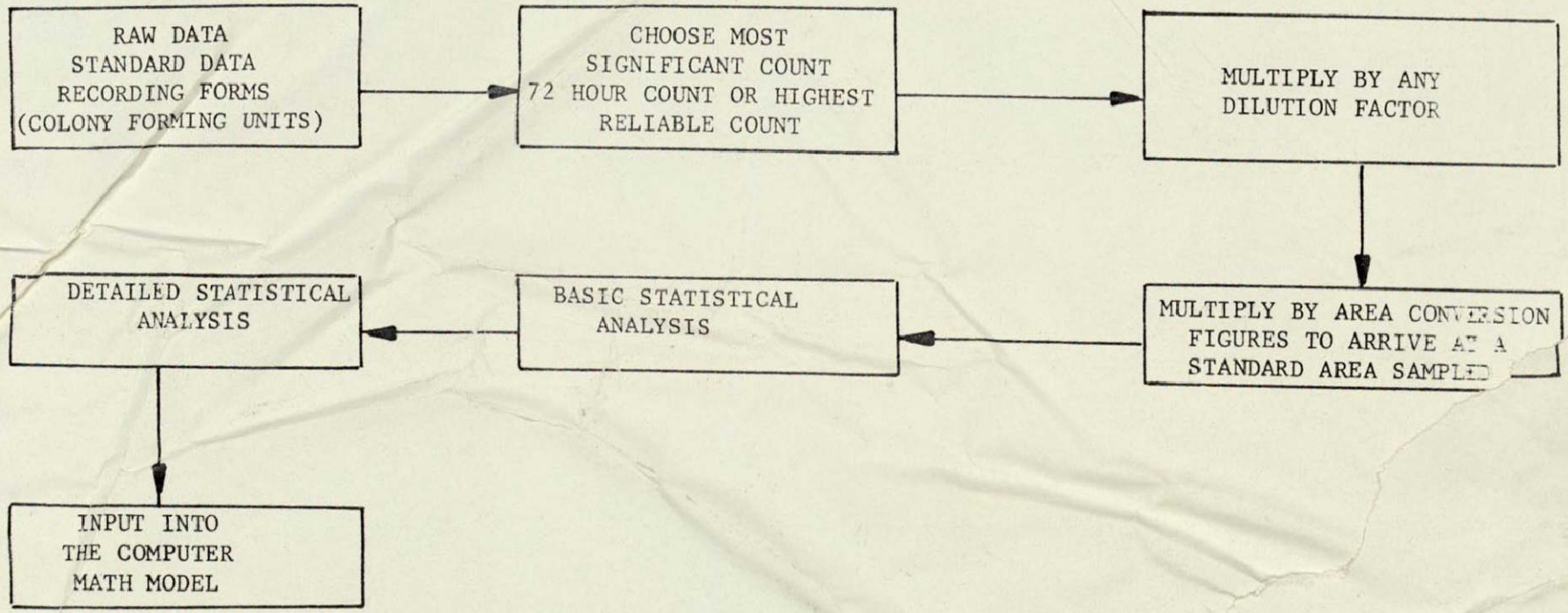


Figure A-15. Flow Chart for Data Reduction